



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-000

March 4, 2016

CEFLA S.C.  
c/o Mr. Maurizio Pantaleoni  
CEO  
ISEMED srl  
Via Altobelli Bonetti 3/a  
IMOLA (BO), ITALY 40026

Re: K151597  
Trade/Device Name: Family of Steam Sterilizer B28 series  
Regulation Number: 21 CFR 880.6880  
Regulation Name: Steam Sterilizer  
Regulatory Class: II  
Product Code: FLE  
Dated: February 1, 2016  
Received: February 4, 2016

Dear Mr. Pantaleoni,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

***Tejashri Purohit-Sheth, M.D.***

**Tejashri Purohit-Sheth, M.D.**  
**Clinical Deputy Director**  
**DAGRID/ODE/CDRH FOR**

Erin I. Keith, M.S.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151597

Device Name

Family of Steam sterilizers B28 series

### Indications for Use (Describe)

The Family of steam Sterilizers B 28 series B CLASSIC-28 and B FUTURA-28 models are table top steam sterilizers to be used in medical and dental practices, hospitals, clinics, nursing homes, laboratories and other facilities to sterilize re-usable surgical instruments (including dental handpieces) and medical materials, heat and moisture resistant and compatible with steam sterilization process.

The Family of Steam Sterilizers B 28 series is validated for sterilization of fabric packs/textiles for sterilization programs C1 and C2.

The Family of Steam Sterilizers B 28 series is validated for sterilization up to 9 dental handpieces for sterilization programs C1 and C2.

The Family of Steam Sterilizers B 28 series is validated for sterilization up to 6 lumen devices (specifications in the table below)

The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.

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The steam sterilizers are available in the following models / brandnames :

|                                      |                                   |                                    |                                        |                                        |
|--------------------------------------|-----------------------------------|------------------------------------|----------------------------------------|----------------------------------------|
| <b>B Classic-28 model – 120 VOLT</b> | <b>MOCOM<br/>commercial brand</b> | <b>ANTHOS<br/>commercial brand</b> | <b>STERNWEBER<br/>commercial brand</b> | <b>CASTELLINI<br/>commercial brand</b> |
| <b>B Futura-28 model -120 VOLT</b>   | <b>MOCOM<br/>commercial brand</b> | <b>ANTHOS<br/>commercial brand</b> | <b>STERNWEBER<br/>commercial brand</b> | <b>CASTELLINI<br/>commercial brand</b> |

[Table 1 – Different models available for Steam sterilizers](#)

The full list of codes included in this submission is listed in the [table 2](#) below:

| <b>Code</b> | <b>Model</b>             | <b>Commercial Brand Name</b> |
|-------------|--------------------------|------------------------------|
| M7A730010   | B Classic-28<br>120 Volt | MOCOM - B Classic-28         |
| M7A770010   | B Futura-28<br>120 Volt  | MOCOM - B Futura-28          |
| 7A173010    | B Classic-28<br>120 Volt | STERN WEBER - SW-28          |
| 7A177010    | B Futura-28<br>120 Volt  | STERN WEBER - SW-28 PLUS     |
| 7A073010    | B Classic-28<br>120 Volt | ANTHOS - A-28                |
| 7A077010    | B Futura-28<br>120 Volt  | ANTHOS - A-28 PLUS           |
| C7A730010   | B Classic-28<br>120 Volt | CASTELLINI - C-28            |
| C7A770010   | B Futura-28<br>120 Volt  | CASTELLINI - C-28 PLUS       |

[Table 2 – List of codes of steam sterilizers and relation with the commercial brand name](#)

Program description, cycle times, temperature and dry time for each model are described in the tables below:

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**B CLASSIC-28 model (B Classic-28; A-28; SW-28; C-28)**

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Chamber Dimensions (Depth 450mm / Diameter 280mm / Volume 27.7 litres)

| PROGRAM NAME                        | CYCLE TYPE                                 | STERILIZATION TEMPERATURE and TIME | DRYING TIME (*) | MAXIMUM LOAD (**) (***)                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------------|--------------------------------------------|------------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (C1)<br>UNIVERSAL<br>134            | PREVACUUM<br>(3 steps; -0.8 bar each step) | 134°C / 273°F<br>4 minutes         | 14.5 min        | 5 kg unwrapped metal or polymer instruments and dental handpieces (max 0.9 kg per tray)<br>2.5kg single package metal or polymer instruments and dental handpieces (max 0.9 kg per tray)<br>1.5kg double package metal or polymer instruments and dental handpieces (max 0.9 kg per tray)<br>1 kg unwrapped porous and fabric textiles<br>0.75 kg single package porous and fabric textiles<br>0.6kg double package porous and fabric textiles |
| (C2)<br>UNIVERSAL<br>121            | PREVACUUM<br>(3 steps; -0.8 bar each step) | 121°C / 250°F<br>20 minutes        | 14.5 min        | 5 kg unwrapped metal or polymer instruments and dental handpieces (max 0.9kg per tray)<br>2.5kg single package metal or polymer instruments and dental handpieces (max 0.9kg per tray)<br>1.5kg double package metal or polymer instruments and dental handpieces (max 0.9kg per tray)<br>1 kg unwrapped porous and fabric textiles<br>0.75 kg single package porous and fabric textiles<br>0.6kg double package porous and fabric textiles    |
| (C4) SOLID<br>134                   | PREVACUUM<br>(1 step; -0.8 bar)            | 134°C / 273°F<br>4 minutes         | 14.5 min        | 5 kg unwrapped metal or polymer instruments (max 0.9kg per tray)<br>2.5kg single package metal or polymer instruments (max 0.9kg per tray)                                                                                                                                                                                                                                                                                                     |
| (C5)<br>HOLLOW<br>134               | PREVACUUM<br>(3 steps; -0.8 bar each step) | 134°C / 273°F<br>4 minutes         | 3 min           | 5 kg unwrapped metal or polymer instruments (max 0.9kg per tray)                                                                                                                                                                                                                                                                                                                                                                               |
| HELIX/BD<br>TEST                    | PREVACUUM<br>(3 steps; -0.8 bar each step) | 134°C / 273°F<br>3.5 minutes       | 1.5 min         | Test device only (without another load)                                                                                                                                                                                                                                                                                                                                                                                                        |
| VACUUM<br>TEST                      | Vacuum<br>(-0.8 bar)                       | /                                  | /               | Empty chamber<br>Vacuum -0.8 bar<br>Test Time: 27 min                                                                                                                                                                                                                                                                                                                                                                                          |
| VACUUM +<br>HELIX/BD<br>TEST (****) | /                                          | /                                  | /               | /                                                                                                                                                                                                                                                                                                                                                                                                                                              |

Table 3 – B-CLASSIC 28 Factory programmed sterilization cycles and parameters

(\*) Default drying time, but the drying time can be manually increased

(\*\*) Cycles C1 and C2 are validated to sterilize up to 6 single sided lumened devices no longer than 118 mm and no smaller than 0.8 mm(corresponding to “hollow A” cavities with a length/diameter (L/D) ratio =  $1 \leq L/D \leq 750$ ). Cycles C4 and C5 are validated to sterilize up to 6 double sided lumened devices no longer than 115 mm and no smaller than 10 mm .

(\*\*\*) If the material is sterilized “unwrapped” the sterilized material shall used immediately after sterilization (the cycle shall be considered as immediate use cycle)

(\*\*\*\*) This program enables to execute, in sequence, Vacuum test and Helix/BD test (nevertheless each test is executed separately)

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**B Futura-28 model (B Futura-28; A-28 PLUS; SW-28 PLUS; C-28 PLUS)**

Chamber Dimensions (Depth 450mm / Diameter 280mm / Volume 27.7 litres)

| PROGRAM NAME                  | CYCLE TYPE                              | STERILIZATION TEMPERATURE and TIME | DRYING TIME (*) | MAXIMUM LOAD (**) (***)                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------|-----------------------------------------|------------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (C1) UNIVERSAL 134            | PREVACUUM (3 steps; -0.8 bar each step) | 134°C / 273°F<br>4 minutes         | 11.5 min        | 5 kg unwrapped metal or polymer instruments and dental handpieces (max 0.9 kg per tray)<br>2.5kg single package metal or polymer instruments and dental handpieces (max 0.9 kg per tray)<br>1.5kg double package metal or polymer instruments and dental handpieces (max 0.9 kg per tray)<br>1 kg unwrapped porous and fabric textiles<br>0.75 kg single package porous and fabric textiles<br>0.6kg double package porous and fabric textiles |
| (C2) UNIVERSAL 121            | PREVACUUM (3 steps; -0.8 bar each step) | 121°C / 250°F<br>20 minutes        | 11.5 min        | 5 kg unwrapped metal or polymer instruments and dental handpieces (max 0.9kg per tray)<br>2.5kg single package metal or polymer instruments and dental handpieces (max 0.9kg per tray)<br>1.5kg double package metal or polymer instruments and dental handpieces (max 0.9kg per tray)<br>1 kg unwrapped porous and fabric textiles<br>0.75 kg single package porous and fabric textiles<br>0.6kg double package porous and fabric textiles    |
| (C4) SOLID 134                | PREVACUUM (1 step; -0.8 bar)            | 134°C / 273°F<br>4 minutes         | 11.5 min        | 5 kg unwrapped metal or polymer instruments (max 0.9kg per tray)<br>2.5kg single package metal or polymer instruments (max 0.9kg per tray)                                                                                                                                                                                                                                                                                                     |
| (C5) HOLLOW 134               | PREVACUUM (3 steps; -0.8 bar each step) | 134°C / 273°F<br>4 minutes         | 3 min           | 5 kg unwrapped metal or polymer instruments (max 0.9kg per tray)                                                                                                                                                                                                                                                                                                                                                                               |
| HELIX/BD TEST                 | PREVACUUM (3 steps; -0.8 bar each step) | 134°C / 273°F<br>3.5 minutes       | 1.33 min        | Test device only (without another load)                                                                                                                                                                                                                                                                                                                                                                                                        |
| VACUUM TEST                   | Vacuum (-0.8 bar)                       | /                                  | /               | Empty chamber<br>Vacuum -0.8 bar<br>Test Time: 27 min                                                                                                                                                                                                                                                                                                                                                                                          |
| VACUUM + HELIX/BD TEST (****) | /                                       | /                                  | /               | /                                                                                                                                                                                                                                                                                                                                                                                                                                              |

Table 4 – B-FUTURA 28 Factory programmed sterilization cycles and parameters

(\*) Default drying time, but the drying time can be manually increased

(\*\*) Cycles C1 and C2 are validated to sterilize up to 6 single sided lumened devices no longer than 118 mm and no smaller than 0.8 mm (corresponding to “hollow A” cavities with a length/diameter (L/D) ratio =  $1 \leq L/D \leq 750$ ). Cycles C4 and C5 are validated to sterilize up to 6 double sided lumened devices no longer than 115 mm and no smaller than 10 mm .

(\*\*\*) If the material is sterilized “unwrapped” the sterilized material shall used immediately after sterilization (the cycle shall be considered as immediate use cycle)

(\*\*\*\*) This program enables to execute, in sequence, Vacuum test and Helix/BD test (nevertheless each test is executed separately)

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Type of Use (*Select one or both, as applicable*)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## 510(k) Summary – K151597

### Family of steam sterilizers B 28 series

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

#### 2.1. General Information

Submitter:

CEFLA SC  
Via Selice Provinciale, 23/A  
40026 - IMOLA (BO)  
ITALY

Establishment Registration Number: 3006610845

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Email: regulatory@isemed.eu

Summary Preparation Date:

February 01, 2016

#### 2.2. Names

Device Name:

Family of Steam sterilizer B28 series

Classification Name:

Steam Sterilizer

Product Code:

FLE

Regulation number:

880.6880

Class:

II

#### 2.3. Predicate Devices

The Family of steam sterilizers B 28 series is substantially equivalent to the following legally marketed predicate device:

| <i>Applicant</i>         | <i>Device name</i>                                          | <i>510(k) Number</i> |
|--------------------------|-------------------------------------------------------------|----------------------|
| M.O.COM. s.r.l           | MILLENNIUM series (B <sup>2</sup> model)                    | K050263              |
| Tuttnauer USA Co.<br>Ltd | Tuttnauer Pre-Vacuum Tabletop<br>Autoclave (Model ELARA-11) | K143311              |

#### 2.4. Intended Use

The Family of steam Sterilizers B 28 series B CLASSIC-28 and B FUTURA-28 models are table top steam sterilizers to be used in medical and dental practices, hospitals, clinics, nursing homes, laboratories and other facilities to sterilize re-usable surgical instruments (including dental handpieces) and medical materials, heat and moisture resistant and compatible with steam sterilization process.

The Family of Steam Sterilizers B 28 series is validated for sterilization of fabric packs/textiles for sterilization programs C1 and C2.

The Family of Steam Sterilizers B 28 series is validated for sterilization up to 9 dental handpieces for sterilization programs C1 and C2.

The Family of Steam Sterilizers B 28 series is validated for sterilization up to 6 lumen devices (specifications in the table below).

The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.

## 2.5. Device Description

The Family of steam sterilizers B 28 series includes table-top steam sterilizers that use saturated steam at high pressures and temperatures to kill infectious bio-organisms. The B Classic-28 and B Futura-28 models differ only for some minor characteristics such as color touchscreen, optional Wi-Fi connection, illumination of the working area and Ethernet connection

The steam is generated by a steam generator connected to the sterilization chamber without disconnecting devices. An electric heating element surrounds the chamber for preheating of the chamber and maintaining the temperature. The subject family is characterized by a fractionated vacuum system for the complete air removal also from hollow and porous materials as well as by a final vacuum drying phase able to eliminate any trace of condensation from the load.

The steam sterilizers are available in the following models / brandnames :

|                                      |                                   |                                    |                                        |                                        |
|--------------------------------------|-----------------------------------|------------------------------------|----------------------------------------|----------------------------------------|
| <b>B Classic-28 model – 120 VOLT</b> | <b>MOCOM<br/>commercial brand</b> | <b>ANTHOS<br/>commercial brand</b> | <b>STERNWEBER<br/>commercial brand</b> | <b>CASTELLINI<br/>commercial brand</b> |
| <b>B Futura-28 model -120 VOLT</b>   | <b>MOCOM<br/>commercial brand</b> | <b>ANTHOS<br/>commercial brand</b> | <b>STERNWEBER<br/>commercial brand</b> | <b>CASTELLINI<br/>commercial brand</b> |

Table 1 – Different models available for Steam sterilizers

The full list of codes included in this submission is listed in the [table 2](#) below:

| Code      | Model        | Commercial Brand Name    |
|-----------|--------------|--------------------------|
| M7A730010 | B Classic-28 | MOCOM - B Classic-28     |
| M7A770010 | B Futura-28  | MOCOM - B Futura-28      |
| 7A173010  | B Classic-28 | STERN WEBER - SW-28      |
| 7A177010  | B Futura-28  | STERN WEBER - SW-28 PLUS |
| 7A073010  | B Classic-28 | ANTHOS - A-28            |
| 7A077010  | B Futura-28  | ANTHOS - A-28 PLUS       |
| C7A730010 | B Classic-28 | CASTELLINI - C-28        |
| C7A770010 | B Futura-28  | CASTELLINI - C-28 PLUS   |

Table 2 – List of codes of steam sterilizers and relation with the commercial brand name

Program description, cycle times, temperature and dry time for each model are described in the tables below:

**B Classic-28 model (B Classic-28; A-28; SW-28; C-28)**

Chamber Dimensions (Depth 450mm / Diameter 280mm / Volume 27,7 litres)

| PROGRAM NAME                  | CYCLE TYPE                              | STERILIZATION TEMPERATURE and TIME | DRYING TIME (*) | MAXIMUM LOAD (**) (***)                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------|-----------------------------------------|------------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (C1) UNIVERSAL 134            | PREVACUUM (3 steps; -0.8 bar each step) | 134°C / 273°F<br>4 minutes         | 14.5 min        | 5 kg unwrapped metal or polymer instruments and dental handpieces (max 0.9 kg per tray)<br>2.5kg single package metal or polymer instruments and dental handpieces (max 0.9 kg per tray)<br>1.5kg double package metal or polymer instruments and dental handpieces (max 0.9 kg per tray)<br>1 kg unwrapped porous and fabric textiles<br>0.75 kg single package porous and fabric textiles<br>0.6kg double package porous and fabric textiles |
| (C2) UNIVERSAL 121            | PREVACUUM (3 steps; -0.8 bar each step) | 121°C / 250°F<br>20 minutes        | 14.5 min        | 5 kg unwrapped metal or polymer instruments and dental handpieces (max 0.9kg per tray)<br>2.5kg single package metal or polymer instruments and dental handpieces (max 0.9kg per tray)<br>1.5kg double package metal or polymer instruments and dental handpieces (max 0.9kg per tray)<br>1 kg unwrapped porous and fabric textiles<br>0.75 kg single package porous and fabric textiles<br>0.6kg double package porous and fabric textiles    |
| (C4) SOLID 134                | PREVACUUM (1 step; -0.8 bar)            | 134°C / 273°F<br>4 minutes         | 14.5 min        | 5 kg unwrapped metal or polymer instruments (max 0.9kg per tray)<br>2.5kg single package metal or polymer instruments (max 0.9kg per tray)                                                                                                                                                                                                                                                                                                     |
| (C5) HOLLOW 134               | PREVACUUM (3 steps; -0.8 bar each step) | 134°C / 273°F<br>4 minutes         | 3 min           | 5 kg unwrapped metal or polymer instruments (max 0.9kg per tray)                                                                                                                                                                                                                                                                                                                                                                               |
| HELIX/BD TEST                 | PREVACUUM (3 steps; -0.8 bar each step) | 134°C / 273°F<br>3.5 minutes       | 1.5 min         | Test device only (without another load)                                                                                                                                                                                                                                                                                                                                                                                                        |
| VACUUM TEST                   | Vacuum (-0.8 bar)                       | /                                  | /               | Empty chamber<br>Vacuum -0.8 bar<br>Test Time: 27 min                                                                                                                                                                                                                                                                                                                                                                                          |
| VACUUM + HELIX/BD TEST (****) | /                                       | /                                  | /               | /                                                                                                                                                                                                                                                                                                                                                                                                                                              |

Table 3 – B-CLASSIC 28 Factory programmed sterilization cycles and parameters

(\*) Default drying time, but the drying time can be manually increased

(\*\*) Cycles C1 and C2 are validated to sterilize up to 6 single sided lumened devices no longer than 118 mm and no smaller than 0.8 mm(corresponding to “hollow A” cavities with a length/diameter (L/D) ratio =  $1 \leq L/D \leq 750$ ). Cycles C4 and C5 are validated to sterilize up to 6 double sided lumened devices no longer than 115 mm and no smaller than 10 mm .

(\*\*\*) If the material is sterilized “unwrapped” the sterilized material shall used immediately after sterilization (the cycle shall be considered as immediate use cycle)

(\*\*\*\*) This program enables to execute, in sequence, Vacuum test and Helix/BD test (nevertheless each test is executed separately)

**B Futura-28 model (B Futura-28; A-28 PLUS; SW-28 PLUS; C-28 PLUS)**

Chamber Dimensions (Depth 450mm / Diameter 280mm / Volume 27,7 litres)

| PROGRAM NAME                  | CYCLE TYPE                              | STERILIZATION TEMPERATURE and TIME | DRYING TIME (*) | MAXIMUM LOAD (**) (***)                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------|-----------------------------------------|------------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (C1) UNIVERSAL 134            | PREVACUUM (3 steps; -0.8 bar each step) | 134°C / 273°F<br>4 minutes         | 11.5 min        | 5 kg unwrapped metal or polymer instruments and dental handpieces (max 0.9 kg per tray)<br>2.5kg single package metal or polymer instruments and dental handpieces (max 0.9 kg per tray)<br>1.5kg double package metal or polymer instruments and dental handpieces (max 0.9 kg per tray)<br>1 kg unwrapped porous and fabric textiles<br>0.75 kg single package porous and fabric textiles<br>0.6kg double package porous and fabric textiles |
| (C2) UNIVERSAL 121            | PREVACUUM (3 steps; -0.8 bar each step) | 121°C / 250°F<br>20 minutes        | 11.5 min        | 5 kg unwrapped metal or polymer instruments and dental handpieces (max 0.9kg per tray)<br>2.5kg single package metal or polymer instruments and dental handpieces (max 0.9kg per tray)<br>1.5kg double package metal or polymer instruments and dental handpieces (max 0.9kg per tray)<br>1 kg unwrapped porous and fabric textiles<br>0.75 kg single package porous and fabric textiles<br>0.6kg double package porous and fabric textiles    |
| (C4) SOLID 134                | PREVACUUM (1 step; -0.8 bar)            | 134°C / 273°F<br>4 minutes         | 11.5 min        | 5 kg unwrapped metal or polymer instruments (max 0.9kg per tray)<br>2.5kg single package metal or polymer instruments (max 0.9kg per tray)                                                                                                                                                                                                                                                                                                     |
| (C5) HOLLOW 134               | PREVACUUM (3 steps; -0.8 bar each step) | 134°C / 273°F<br>4 minutes         | 3 min           | 5 kg unwrapped metal or polymer instruments (max 0.9kg per tray)                                                                                                                                                                                                                                                                                                                                                                               |
| HELIX/BD TEST                 | PREVACUUM (3 steps; -0.8 bar each step) | 134°C / 273°F<br>3.5 minutes       | 1.33 min        | Test device only (without another load)                                                                                                                                                                                                                                                                                                                                                                                                        |
| VACUUM TEST                   | Vacuum (-0.8 bar)                       | /                                  | /               | Empty chamber<br>Vacuum -0.8 bar<br>Test Time: 27 min                                                                                                                                                                                                                                                                                                                                                                                          |
| VACUUM + HELIX/BD TEST (****) | /                                       | /                                  | /               | /                                                                                                                                                                                                                                                                                                                                                                                                                                              |

Table 4 – B-FUTURA 28 Factory programmed sterilization cycles and parameters

(\*) Default drying time, but the drying time can be manually increased

(\*\*) Cycles C1 and C2 are validated to sterilize up to 6 single sided lumened devices no longer than 118 mm and no smaller than 0.8 mm(corresponding to “hollow A” cavities with a length/diameter (L/D) ratio =  $1 \leq L/D \leq 750$ ). Cycles C4 and C5 are validated to sterilize up to 6 double sided lumened devices no longer than 115 mm and no smaller than 10 mm .

(\*\*\*) If the material is sterilized “unwrapped” the sterilized material shall used immediately after sterilization (the cycle shall be considered as immediate use cycle)

(\*\*\*\*) This program enables to execute, in sequence, Vacuum test and Helix/BD test (nevertheless each test is executed separately)

## 2.6. Nonclinical Comparison to predicate devices.

| Features                                 | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Predicate Devices                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Substantially Equivalent |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|                                          | B FUTURA-28<br>B CLASSIC-28                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | MOCOM – Millennium<br>Series B <sup>2</sup> model<br>K050263                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Tuttnauer Pre-Vacuum<br>Tabletop Autoclave<br>ELARA-11 K143311                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                          |
| CFR code                                 | 880.6880 – Steam Sterilizers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 880.6880 – Steam Sterilizers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 880.6880 – Steam Sterilizers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | same                     |
| Class                                    | II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | same                     |
| Product code                             | FLE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | FLE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | FLE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | same                     |
| Indication for use                       | <p>The Family of steam Sterilizers B 28 series B CLASSIC-28 and B FUTURA-28 models are table top steam sterilizers to be used in medical and dental practices, hospitals, clinics, nursing homes, laboratories and other facilities to sterilize re-usable surgical instruments (including dental handpieces) and medical materials, heat and moisture resistant and compatible with steam sterilization process.</p> <p>The Family of Steam Sterilizers B 28 series is validated for sterilization of fabric packs/textiles for sterilization programs C1 and C2</p> <p>The Family of Steam Sterilizers B 28 series is validated for sterilization up to 9 dental handpieces for sterilization programs C1 and C2.</p> <p>The Family of Steam Sterilizers B 28 series is validated for sterilization up to 6 lumen devices</p> <p>The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products</p> | <p>The device is intended to be used in medical and dental practices, hospitals, clinics, nursing homes, laboratories and other facilities to sterilize re-usable surgical instruments (including dental handpieces) and medical materials, heat and moisture resistant and compatible with steam sterilization process.</p> <p>Typical users of this system are trained professionals including, but not limited to, dentists, nurses and other specific medical professionals.</p> <p>NOTE: The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.</p> | <p>The ELARA-11 is a table-top autoclave designed for sterilizing medical and surgical goods, including both wrapped and unwrapped, solid, hollow, and porous products and goods defined as hollow A (e.g., dental hand pieces; suction pipes) in ophthalmic, dental, medical clinics; and in first aid rooms.</p> <p>The ELARA-11 is validated for use in sterilizing lumened device if no longer than 230 mm and no smaller than 3.4 mm for sterilization programs 2 and 4.</p> <p>The ELARA-11 is validated for use in sterilizing fabric packs/textiles for sterilization programs 2 and 4.</p> <p>The ELARA-11 is validated for use in sterilizing up to six dental handpieces for sterilization programs 2 and 4</p> | equivalent               |
| <b>Construction</b>                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                          |
| Chamber Volume usable                    | 28 litres<br>(19 litres with tray supports inserted)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 21 litres<br>(13 litres with tray supports inserted)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 28.5 litres                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | equivalent               |
| Sterilization Chamber dimensions (Ø x H) | 280 x 450 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 250 x 450 mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 220 x 502mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | equivalent               |

| Features                                    | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                 | Predicate Devices                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                | Substantially Equivalent |
|---------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|                                             | B FUTURA-28<br>B CLASSIC-28                                                                                                                                                                                                                                                                                                                                                                                                    | MOCOM – Millennium<br>Series B <sup>2</sup> model<br>K050263                                                                                                                                                                                                                                                                                                                                                                   | Tuttnauer Pre-Vacuum<br>Tabletop Autoclave<br>ELARA-11 K143311                                                                                                                                                                                                                                                                                                                                                                 |                          |
| <b>Design</b>                               |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                |                          |
| Operating principle                         | The sterilizing agent is steam made from demineralized water. Steam is commonly used to sterilize porous and non porous heat resistant materials / textiles for more than 100 years. Sterilization temperatures are 121°C / 250 °F and 134°C / 273 °F.                                                                                                                                                                         | The sterilizing agent is steam made from demineralized water. Steam is commonly used to sterilize porous and non porous heat resistant materials / textiles for more than 100 years. Sterilization temperatures are 121°C / 250 °F and 134°C / 273 °F.                                                                                                                                                                         | Sterilization using steam as the sterilizing agent                                                                                                                                                                                                                                                                                                                                                                             | same                     |
| Mechanism of action for steam sterilization | Saturated steam contacts the surface of the device and is able to sterilize it, since saturated steam is able to denature the membrane and the proteins of microorganisms and spores. In case of packaged devices or of devices with lumens (e.g. dental handpieces), the steam penetrates through the packaging and into the lumens, by means of the air removal due to the vacuum pump, and is able to sterilize the devices | Saturated steam contacts the surface of the device and is able to sterilize it, since saturated steam is able to denature the membrane and the proteins of microorganisms and spores. In case of packaged devices or of devices with lumens (e.g. dental handpieces), the steam penetrates through the packaging and into the lumens, by means of the air removal due to the vacuum pump, and is able to sterilize the devices | Saturated steam contacts the surface of the device and is able to sterilize it, since saturated steam is able to denature the membrane and the proteins of microorganisms and spores. In case of packaged devices or of devices with lumens (e.g. dental handpieces), the steam penetrates through the packaging and into the lumens, by means of the air removal due to the vacuum pump, and is able to sterilize the devices | same                     |
| Sterilization cycle type                    | All cycles are pre-vacuum with post vacuum drying                                                                                                                                                                                                                                                                                                                                                                              | All cycles are pre-vacuum with post vacuum drying                                                                                                                                                                                                                                                                                                                                                                              | All cycles are pre-vacuum with post vacuum drying                                                                                                                                                                                                                                                                                                                                                                              | equivalent               |
| Device SW controlled                        | Yes                                                                                                                                                                                                                                                                                                                                                                                                                            | Yes                                                                                                                                                                                                                                                                                                                                                                                                                            | Yes                                                                                                                                                                                                                                                                                                                                                                                                                            | same                     |
| Built according to standard                 | ANSI/AAMI ST55:2010 Table-top steam sterilizers                                                                                                                                                                                                                                                                                                                                                                                | ANSI/AAMI ST55:2003 Table-top steam sterilizers                                                                                                                                                                                                                                                                                                                                                                                | ANSI/AAMI ST55:2010 Table-top steam sterilizers                                                                                                                                                                                                                                                                                                                                                                                | equivalent               |
| Electrical safety standard                  | IEC 61010-1:2001 (edition 2) / UL 61010-1 2 <sup>nd</sup> edition IEC 61010-2-040: 2005 (edition 1) for use in conjunction with IEC 61010-1:2001 (ed. 2)                                                                                                                                                                                                                                                                       | IEC 61010-1:2001 (edition 2) / UL 61010-1 2 <sup>nd</sup> edition IEC 1010-2-041: 1995 (1st Edition)                                                                                                                                                                                                                                                                                                                           | IEC 61010-1:2001 (edition 2) / UL 61010-1 2 <sup>nd</sup> edition IEC 61010-2-040: 2005 (edition 1) for use in conjunction with IEC 61010-1:2001 (ed. 2)                                                                                                                                                                                                                                                                       | equivalent               |
| EMC conformity                              | IEC 61326-1:2012                                                                                                                                                                                                                                                                                                                                                                                                               | IEC 61326-1:2006                                                                                                                                                                                                                                                                                                                                                                                                               | Unknown                                                                                                                                                                                                                                                                                                                                                                                                                        | equivalent               |
| Heaters                                     | An heating foil pre heats the sterilization chamber and maintains the temperature for the sterilization and drying processes                                                                                                                                                                                                                                                                                                   | An heating foil pre heats the sterilization chamber and maintains the temperature for the sterilization and drying processes                                                                                                                                                                                                                                                                                                   | pre-heating of the sterilization chamber                                                                                                                                                                                                                                                                                                                                                                                       | equivalent               |
| Steam Generator                             | An external steam generator produces steam through a dedicated heater                                                                                                                                                                                                                                                                                                                                                          | An external steam generator produces steam through a dedicated heater                                                                                                                                                                                                                                                                                                                                                          | steam generator produces steam through a dedicated heater                                                                                                                                                                                                                                                                                                                                                                      | equivalent               |

| Features                                       | Subject Device                                                                                                                                                                                                                                                                                                                                                                        | Predicate Devices                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                       | Substantially Equivalent |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|                                                | B FUTURA-28<br>B CLASSIC-28                                                                                                                                                                                                                                                                                                                                                           | MOCOM – Millennium<br>Series B <sup>2</sup> model<br>K050263                                                                                                                                                                                                                                                                                                  | Tuttnauer Pre-Vacuum<br>Tabletop Autoclave<br>ELARA-11 K143311                                                                                                                                                                                                                                                                        |                          |
| Vacuum Device                                  | Membrane vacuum pump with max free air flow of 38 litres per minute (B Futura) or 20 litres per minute (B Classic)                                                                                                                                                                                                                                                                    | Membrane vacuum pump with max free air flow of 20 litres per minute                                                                                                                                                                                                                                                                                           | Vacuum pump                                                                                                                                                                                                                                                                                                                           | equivalent               |
| Air filtration                                 | 0.027 µm, efficiency: 99.999% efficiency: 99.97% for 0.3-micron particles                                                                                                                                                                                                                                                                                                             | 0.027 µm, efficiency: 99.999% efficiency: 99.97% for 0.3-micron particles                                                                                                                                                                                                                                                                                     | 0.2 µm filter                                                                                                                                                                                                                                                                                                                         | equivalent               |
| Chamber:                                       | <u>Construction material:</u> Austenitic Stainless Steel.<br><u>Design Pressure:</u> 2.4 bar / 34.8 psi (relative pressure)<br><u>Design Standard:</u> Conforming to ASME BPVC Section 8, Division 2                                                                                                                                                                                  | <u>Construction material:</u> Austenitic Stainless Steel.<br><u>Design Pressure:</u> 2.4 bar / 34.8 psi (relative pressure)<br><u>Design Standard:</u> Conforming to ASME BPVC Section 8, Division 1                                                                                                                                                          | <u>Construction material:</u> Austenitic Stainless Steel.<br><u>Design Pressure:</u> 2.8 bar / 40 psi<br><u>Design Standard:</u> Conforming to ASME BPVC Section 8, Division 1                                                                                                                                                        | equivalent               |
| Process parameters / Process Control           | Sterilization cycle is controlled by time, temperature and pressure and are recorded on printout. The process is controlled automatically through all the phases of the cycle                                                                                                                                                                                                         | Sterilization cycle is controlled by time, temperature and pressure and are recorded on printout. The process is controlled automatically through all the phases of the cycle                                                                                                                                                                                 | Sterilization cycle is controlled by time, temperature and pressure and are recorded on printout. The process is controlled automatically through all the phases of the cycle                                                                                                                                                         | equivalent               |
| Process parameters displayed on control panel: | <u>At cycle start:</u><br>total number of cycles<br>set Sterilization temperature<br>set Holding time<br><u>During the cycle:</u><br>cycle time countdown<br>real time temperature<br>real time pressure.<br><u>At the end of the cycle:</u><br>Cycle outcome (positive or negative)<br>min/max temperature during sterilization phase<br>min/max pressure during sterilization phase | <u>At cycle start:</u><br>total number of cycles<br>set Sterilization temperature<br>set Holding time<br><u>During the cycle:</u><br>real time temperature<br>real time pressure.<br><u>At the end of the cycle:</u><br>Cycle outcome (positive or negative)<br>min/max temperature during sterilization phase<br>min/max pressure during sterilization phase | <u>At cycle start:</u><br>total number of cycles<br><u>During the cycle:</u><br>Sterilization temperature<br>Sterilization time<br>Dry time<br>Chamber temperature<br>Chamber pressure<br>Steam generator pressure<br>Time display: Clock & Time countdown<br><u>At the end of the cycle:</u><br>Cycle outcome (positive or negative) | equivalent               |
| Process Monitors                               | <ul style="list-style-type: none"> <li>✓ 1 temperature probe in the chamber</li> <li>✓ 1 temperature probe in the heating element</li> <li>✓ 1 temperature probe in the steam generator</li> <li>✓ 1 pressure sensor for sterilization chamber</li> <li>✓ 1 conductivity sensor (water quality)</li> <li>✓ 1 temperature probe in the reservoir</li> </ul>                            | <ul style="list-style-type: none"> <li>✓ 1 temperature probe in the chamber</li> <li>✓ 1 temperature probe in the heating element</li> <li>✓ 1 temperature probe in the steam generator</li> <li>✓ 1 pressure sensor for sterilization chamber</li> </ul>                                                                                                     | <ul style="list-style-type: none"> <li>✓ 1 temperature probe in the chamber</li> <li>✓ 1 temperature probe in the heating element</li> <li>✓ 1 pressure probe in the steam generator</li> <li>✓ 1 pressure sensor for sterilization chamber</li> </ul>                                                                                | equivalent               |

| Features                     | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                   | Predicate Devices                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                     | Substantially Equivalent |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|                              | B FUTURA-28<br>B CLASSIC-28                                                                                                                                                                                                                                                                                                                                                                                                      | MOCOM – Millennium<br>Series B <sup>2</sup> model<br>K050263                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Tuttnauer Pre-Vacuum<br>Tabletop Autoclave<br>ELARA-11 K143311                                                                                                                                                                                                                                                      |                          |
| <b>Performances</b>          |                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                     |                          |
| Biological performance       | SAL of 10 <sup>-6</sup> reduction<br>(no growth at half cycle with validation loads according to AAMI ST55:2010)                                                                                                                                                                                                                                                                                                                 | SAL of 10 <sup>-6</sup> reduction<br>(no growth at half cycle with validation loads according to AAMI ST55:2003)                                                                                                                                                                                                                                                                                                                                                                                                                | SAL of 10 <sup>-6</sup> reduction<br>(no growth at half cycle with validation loads according to AAMI ST55:2010)                                                                                                                                                                                                    | same                     |
| Moisture retention           | <0.5% increase in wrapped instrument test tray<br><2% increase in textile test pack<br>according to AAMI ST55:2010                                                                                                                                                                                                                                                                                                               | <0.5% increase in wrapped instrument test tray<br><2% increase in textile test pack<br>AAMI ST55:2003                                                                                                                                                                                                                                                                                                                                                                                                                           | <0.5% increase in wrapped instrument test tray<br><2% increase in textile test pack<br>according to AAMI ST55:2010                                                                                                                                                                                                  | same                     |
| Process equivalent time (F0) | B FUTURA-28:<br>28.62 (F0 at 121°C – worst case condition)<br>B CLASSIC-28:<br>27.70 (F0 at 121°C – worst case condition)                                                                                                                                                                                                                                                                                                        | 27.66 (F0 at 121°C – worst case condition)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Unknown                                                                                                                                                                                                                                                                                                             | equivalent               |
| <b>Cycle characteristics</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                     |                          |
| Cycle phases comparison      | The cycle is composed by 9 phases that are:<br>1) Preheating generator / chamber<br>2) Vacuum / Steam pulses (1 or 3 times)<br>3) Temperature increase through pressure raise<br>4) Temperature and pressure stabilization<br>5) Sterilization<br>6) Depressurization of sterilization chamber (STEAM DISCHARGE)<br>7) Vacuum-drying phase<br>8) Load ventilation with sterile air<br>9) Bring the pressure to atmospheric level | The cycle is composed by 9 phases that are:<br>1) Pre-heating generator / chamber;<br>2) Vacuum / Steam pulses<br>3) Pressure increasing, with steam temperature raise up to the preset conditions (e.g. 273 °F);<br>4) Stabilization of the pressure and temperature<br>5) Sterilization process for the preset time (e.g. 4 minutes);<br>6) Chamber pressure decreasing through steam discharge;<br>7) Vacuum drying phase;<br>8) Venting phase through sterile air<br>9) Chamber pressure levelling up to atmospheric value. | The cycle is composed by 5 phases that are:<br>1) Vacuum stage followed by introduction of saturated steam<br>2) Heating stage<br>3) Sterilization Stage<br>4) Exhaust stage – steam in exhausted from chamber<br>5) Dry stage followed by vacuum break until the chamber pressure equalize to atmospheric pressure | equivalent               |

| Features                                   | Subject Device                                                                                                                                                                                                                                                                                    | Predicate Devices                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                            | Substantially Equivalent |
|--------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|                                            | B FUTURA-28<br>B CLASSIC-28                                                                                                                                                                                                                                                                       | MOCOM – Millennium<br>Series B <sup>2</sup> model<br>K050263                                                                                                                                                                                                                                                                                                                                                                                                                                             | Tuttnauer Pre-Vacuum<br>Tabletop Autoclave<br>ELARA-11 K143311                                                                                                                                                                                                                                                                                                             |                          |
| Available cycles                           | <ul style="list-style-type: none"> <li>(C1) 134°C universal – 2.1 bar – 4 min cycle</li> <li>(C2) 121°C universal – 1.1 bar – 20 min cycle</li> <li>(C4) 134°C solid wrapped – 2.1 bar – 4 min cycle</li> <li>(C5) 134°C Hollow unwrapped – 2.1 bar – 4 min</li> <li>User Configurable</li> </ul> | <ul style="list-style-type: none"> <li>134°C porous – 2.1 bar – 4 min cycle</li> <li>121°C porous – 1.1 bar – 20 min cycle</li> <li>134°C hollow – 2.1 bar – 4 min cycle</li> <li>121°C hollow – 1.1 bar – 20 min cycle</li> <li>134°C wrapped – 2.1 bar – 4 min cycle</li> <li>121°C wrapped – 1.1 bar – 20 min cycle</li> <li>134°C solid – 2.1 bar – 4 min cycle</li> <li>121°C solid – 1.1 bar – 20 min cycle</li> <li>134°C emergency – 2.1 bar – 3 min cycle</li> <li>User Configurable</li> </ul> | 1- Unwrapped -134C for 4 min.- 1min (dry time) – 25min max total cycle time<br>2- Wrapped -134C for 4min – 20 min (dry time) – 50 min max total cycle time<br>3- Unwrapped/Delicate instruments -121°C for 20 min + 1 min (dry time) - 40min max total cycle time<br>4- Wrapped/Delicate instruments -121°C for 20 minutes + 20min (dry time) – 70min max total cycle time | equivalent               |
| Sterilizable materials / devices           | - unwrapped metal or polymer instruments, dental handpieces, porous and fabric textiles<br>- single and double package metal or polymer instruments, dental handpieces, porous and fabric textiles                                                                                                | -Unpackaged porous, solid materials and hollow instruments / dental handpieces<br>-Porous materials in single and double package<br>-Solid and handpieces in single and double package                                                                                                                                                                                                                                                                                                                   | wrapped and unwrapped, solid, hollow, and porous products and goods defined as hollow A (e.g., dental hand pieces; suction pipes)                                                                                                                                                                                                                                          | equivalent               |
| Sterilization of liquids & pharmaceuticals | NO                                                                                                                                                                                                                                                                                                | NO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | NO                                                                                                                                                                                                                                                                                                                                                                         | same                     |
| Test Programs                              | Vacuum Test<br>Helix / Bowie & Dick Test<br>Vacuum Test + Helix / Bowie & Dick Test                                                                                                                                                                                                               | Vacuum Test,<br>Helix / Bowie & Dick Test,                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Vacuum Test<br>Bowie & Dick Test                                                                                                                                                                                                                                                                                                                                           | equivalent               |
| <b>Sterilization cycle specifications</b>  |                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                            |                          |
| Pre vacuum                                 | Yes (single and fractionated)                                                                                                                                                                                                                                                                     | Yes (single and fractionated)                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | All cycles are pre- vacuum sterilization cycles                                                                                                                                                                                                                                                                                                                            | equivalent               |
| Vacuum drying                              | Yes                                                                                                                                                                                                                                                                                               | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Yes                                                                                                                                                                                                                                                                                                                                                                        | same                     |
| Sterilization temperatures                 | 134°C / 273 °F or 121°C / 250 °F                                                                                                                                                                                                                                                                  | 134°C / 273 °F or 121°C / 250 °F                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 134°C / 273 °F or 121°C / 250 °F                                                                                                                                                                                                                                                                                                                                           | same                     |
| pressure                                   | 31.5 psi or 17 psi                                                                                                                                                                                                                                                                                | 31.5 psi or 17 psi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 31.5 psi or 17 psi                                                                                                                                                                                                                                                                                                                                                         | same                     |
| Sterilization time                         | 4 min (at 273°F) or 20 min (at 250°F)                                                                                                                                                                                                                                                             | 4 min (at 273°F) or 20 min (at 250°F)                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 4 min (at 273°F) or 20 min (at 250°F)                                                                                                                                                                                                                                                                                                                                      | same                     |

| Features                                 | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Predicate Devices                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                | Substantially Equivalent |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
|                                          | B FUTURA-28<br>B CLASSIC-28                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | MOCOM – Millennium<br>Series B <sup>2</sup> model<br>K050263                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Tuttnauer Pre-Vacuum<br>Tabletop Autoclave<br>ELARA-11 K143311                                                                                                                                                 |                          |
| Single/double wrapped max load, kg / lbs | <p>5 kg unwrapped metal or polymer instruments and dental handpieces (max 0.9kg per tray)</p> <p>2.5kg single package metal or polymer instruments and dental handpieces (max 0.9 kg per tray)</p> <p>1.5kg double package metal or polymer instruments and dental handpieces (max 0.9kg per tray)</p> <p>1 kg unwrapped porous and fabric textiles</p> <p>0.75 kg single package porous and fabric textiles</p> <p>0.6kg double package porous and fabric textiles</p> <p>Max N°9 handpieces</p> <p>Max 6 single sided lumen 118 mm x 0,8 or 6 double sided lumen devices no longer than 115 mm and no smaller than 10 mm .</p> | <p>5 kg unwrapped metal or polymer instruments and dental handpieces (max 0.9kg per tray)</p> <p>2.5kg single package metal or polymer instruments and dental handpieces (max 0.9 kg per tray)</p> <p>1.5kg double package metal or polymer instruments and dental handpieces (max 0.9kg per tray)</p> <p>1 kg unwrapped porous and fabric textiles</p> <p>0.75 kg single package porous and fabric textiles</p> <p>0.6kg double package porous and fabric textiles</p> <p>Max N°9 handpieces</p> <p>Max 6 single sided lumen 118 mm x 0,8 or 6 double sided lumen devices no longer than 115 mm and no smaller than 10 mm .</p> | <p>Double wrapped Solid load shall not exceed 8 Kg</p> <p>Double wrapped porous load shall not exceed 2 Kg</p> <p>Maximum load per tray: 2 kg</p> <p>Max N°6 handpieces</p> <p>1 lumen device 230 x 3,4 mm</p> | Equivalent               |
| Indicator Gauges                         | <p>During the cycle the following parameters are displayed on control panel:</p> <ul style="list-style-type: none"> <li>- Temperature</li> <li>- Pressure</li> <li>- Process time</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>During the cycle the following parameters are displayed on control panel:</p> <ul style="list-style-type: none"> <li>- Temperature</li> <li>- Pressure</li> <li>- Process time</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>During the cycle the following parameters are displayed on control panel:</p> <ul style="list-style-type: none"> <li>- Temperature</li> <li>- Pressure</li> <li>- Process time</li> </ul>                   | same                     |
| Printouts                                | <p>A printout / report with all the information about the cycle and sterilization result (POSITIVE / NEGATIVE) is available at the end of each cycle. The report is available in pdf file format (downloadable via USB key) or could be printed by the optional external printer.</p>                                                                                                                                                                                                                                                                                                                                            | <p>A printout / report with all the information about the cycle and sterilization result (POSITIVE / NEGATIVE) is available at the end of each cycle, when the optional integrated printer is available</p>                                                                                                                                                                                                                                                                                                                                                                                                                      | <p>A printout / report with all the information about the cycle and sterilization result (POSITIVE / NEGATIVE) is available at the end of each cycle</p>                                                       | Equivalent               |
| Recorders                                | <p>The cycle report can be printed with the optional printer. Otherwise it can be downloaded through Ethernet or wi-fi connection or through an USB pen .</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>The cycle report is printed through the optional integrated printer, when available</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <p>The cycle report is printed through the integrated printer, when available</p>                                                                                                                              | Equivalent               |

## 2.7.Performance Data

The design and sterilization process have been validated according to the requirements of AAMI ST55:2010. Especially the performed tests include Biological tests that show that the sterilization cycles are able to kill biological indicators assuring a sterility assurance level (SAL) of  $10^{-6}$  reduction.

The results of the tests performed are summarized below:

- The chamber temperature during sterilization has been verified according to AAMI ST55 (points 4.4.3 / 5.4.3) using worst case loads . Chamber temperatures are always between - 0°C and +3°C of the sterilization temperature set point during sterilization holding time. The results are in compliance with the acceptance criteria defined.
- The biological performances with a textile PCD have been verified according to AAMI ST55 (point 5.5.2). All the biological indicators of each cycle tested resulted sterile, ensuring a SAL of  $10^{-6}$ .
- The biological performances with wrapped instruments and lumen devices (double package) have been verified according to AAMI ST55 (point 5.5.4). All the biological indicators of each cycle tested resulted sterile, ensuring a SAL of  $10^{-6}$ .
- The biological performances with dental handpieces (double package) have been verified according to AAMI ST55 (point 5.5.5). All the biological indicators of each cycle tested resulted sterile, ensuring a SAL of  $10^{-6}$ .
- The Bowie Dick Test cycle has been verified using a FDA cleared Bowie-Dick test pack according to AAMI ST55 (point 5.6.1.1). After the test run, the Bowie-Dick test indicator showed a uniform color change.
- The Air Leak test has been performed according to AAMI ST55 (point 5.6.2). After the test run, the average leak rate is < 1mmHg (0,13kPa) which is in compliance with the acceptance criteria defined.
- The moisture retention test has been performed according to AAMI ST55 (points 5.7.1 / 5.7.2). Due to the different drying time the test has been conducted separately on B Classic-28 and B Futura 28 models, using worst case loads and wraps. The results are in compliance with the acceptance criteria defined by ANSI / AAMI ST55 for all the cycles tested.
- Software validation has been performed according to IEC 62304 First Edition 2006-05.
- Safety tests have been performed according to the following standards demonstrating the conformity of the subject device:
  - IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
  - IEC 61010-2-040 Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
- Electromagnetic compatibility tests have been performed according to the following standards demonstrating the conformity of the subject device:
  - IEC 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

## **2.8.Conclusions**

In conclusion, the subject Family of Steam Sterilizers B28 series is substantially equivalent to predicate devices K050263 and K143311. Based on the intended use, technological characteristics, and performance data, the subject device is substantially equivalent and is as safe and as effective as the legally marketed predicate device.