TABLE OF CONTENTS

3.2.3 DEVICE MANUFACTURING 3
3.2.3.1 Device Manufacturing Process 3
3.2.3.1.1 Assembly Process – Introduction 4
3.2.3.1.2 Assembly Flow of the Holder 4
3.2.3.1.3 Assembly Flow of the Charger 5
3.2.3.1.4 Assembly of the Kitted Product 7
3.2.3.2 Specifications 7
3.2.3.2.1 Holder 7
3.2.3.2.2 Charger (Main Unit) 8
3.2.3.3 Manufacturing Control 8
3.2.3.4 Design Verification 9
3.2.3.4.1 Functional Design Specification 9
3.2.3.4.2 Design Verification Plan 9
3.2.3.4.3 Design Test Specifications 9
3.2.3.4.4 Design Test Reports 9
3.2.3.4.5 Design Verification Report 9
3.2.3.4.6 Overview – Design Verification – Activities by Categories 9
3.2.3.5 Packaging 11
3.2.3.6 Compliance with Standards 11

TABLE OF TABLES

Table 1 Facilities Performing Manufacturing and Assembly Activities 3
Table 2 Item Codes of Device under Tests (DUT) 10
Table 3 Use of Standards 12

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TABLE OF FIGURES

Figure 1 Assembly Flow – Holder 5
Figure 2 Assembly Flow – Charger 6
Figure 3 Assembly Flow – Kitted Product 7
Figure 4 Design Verification – Activities Sequence 9
Figure 5 Design Verification – Activities by Functional Test Categories 10

APPENDICES

A3.2.3-1 ISO Certificates – (b) (4)
A3.2.3-2 Device Bill of Materials
A3.2.3-3 Certificates of Conformity for the Device – (b) (4)
A3.2.3-4 Test Certificates

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3.2.3 Device Manufacturing

3.2.3.1 Device Manufacturing Process

The Device assembly activities are coordinated by (b) (4), and assembly activities for THD 2.4 take place at (b) (4) (see Table 1).

The Tobacco Heating Device was designed at PMP S.A. and is manufactured on behalf of PMP S.A. by (b) (4) is an approved supplier to PMP S.A.

Table 1 Facilities Performing Manufacturing and Assembly Activities

Company	Location	Responsibility
Philip Morris Products S.A. (PMP S.A), part of the Philip Morris International group of companies.	Research & Development (Device Development) Quai Jeanrenaud Neuchatel 2000 Switzerland	(b) (4)
Philip Morris International Research Laboratories Pte Ltd (PMIRL), part of the Philip Morris International group of companies.	50 Science Park Road, #02-07 The Kendall Singapore Science Park II Singapore 117406	
(b) (4)		

(b) (4) *Quality Management System*

(b) (4) is certified according to ISO 9001:2008 (see Appendix A3.2.3-1). The Quality Manual in the ISO standard is divided into five categories as described below:

- Scope and Medical Quality Management System (QMS)
- Management Responsibilities
- Resource Management
- Product Realization
- Measurement, Analysis and Improvement

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The categories above provide the structure for the identification of methods, systems and controls employed by the company in manufacturing, assembly, inspection and testing, quality assurance of products and services. Internal audits and management reviews are performed at regular intervals to assess the effectiveness of the QMS.

(b) (4)

(b) (4) is responsible for:

- establishing the process validation master file,
- maintaining the equipment and the facilities for manufacturing,
- providing appropriate training to all the employees as applicable.

(b) (4) is also responsible for implementing any approved design changes which occur following the commercial release of the product by PMI.

3.2.3.1.1 Assembly Process – Introduction

The assembly process can be broken down into three major sections:

1. The manufacture of the components for the Devices, and the manufacture of accessories is performed by approved suppliers. (b) (4) .
2. The final assembly of the Devices takes place at (b) (4) .
3. The packaging activities are performed by (b) (4) .

The assembly flow for work performed by (b) (4) is described in various quality documents (Process Management Plans, Procedures and Work Instructions) which provide detailed descriptions of the specific work steps.

3.2.3.1.2 Assembly Flow of the Holder

The Holder is assembled following the major steps displayed in Figure 1.

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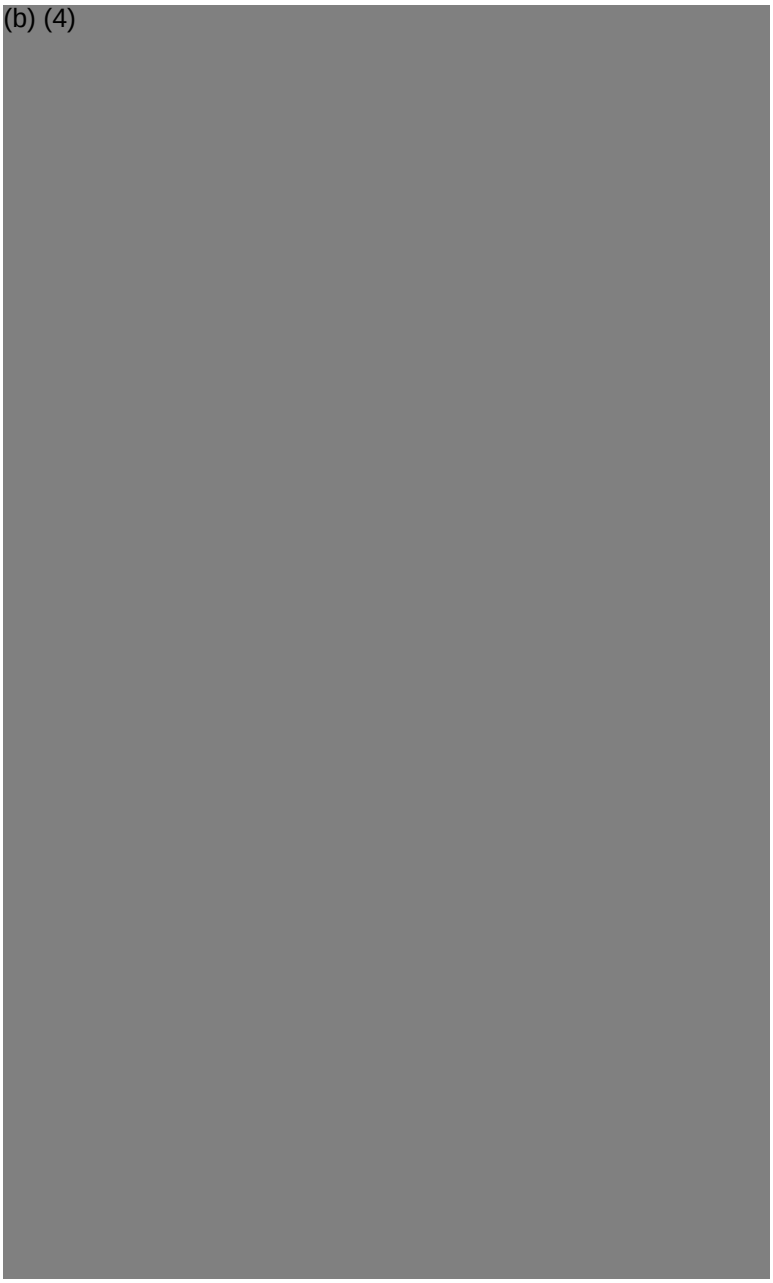


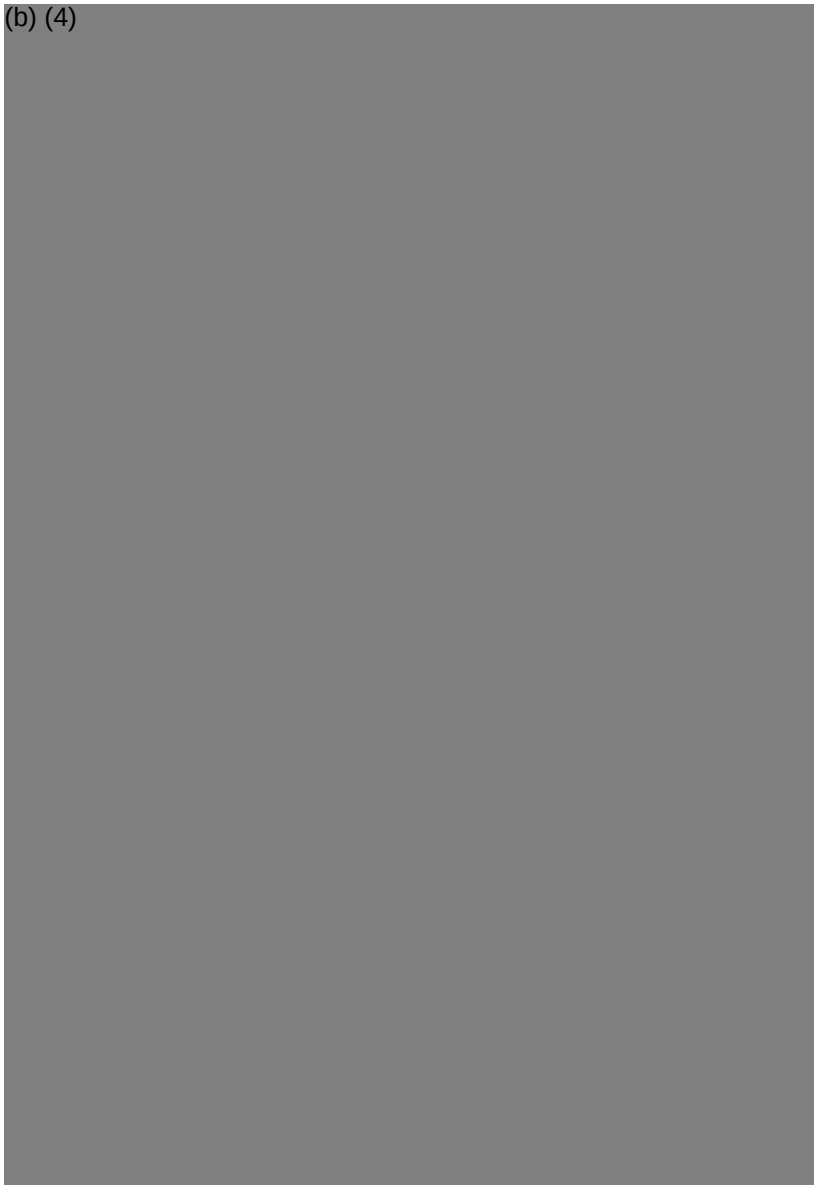
Figure 1 Assembly Flow – Holder

3.2.3.1.3 Assembly Flow of the Charger

The Charger is assembled following the major steps displayed in Figure 2.

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*Codentify is a coding system that was developed to provide product traceability worldwide

Figure 2 Assembly Flow – Charger

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3.2.3.1.4 Assembly of the Kitted Product

During the final assembly, the Holder and Charger are paired and packed into a box with the accessories (see Figure 3). In addition these items can also be packed individually, using the same process flow.



Figure 3 Assembly Flow – Kitted Product

3.2.3.2 Specifications

3.2.3.2.1 Holder

The components and assemblies critical for the function of the Holder are highlighted in Figure 1.

The critical components and assemblies are:



The components and assemblies control the airflow in the Holder and the temperature required to provide the user with aerosol.

Bills of Material describing critical components for the Holder version White Matte and Dark Slate are provided in Appendix A3.2.3-2. This includes not only the components central to the heating performance (such as the heater itself and the control electronics), but also firmware and all the other mechanical and electrical components.

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3.2.3.2.2 Charger (Main Unit)

The components and assemblies critical for the function of the main unit are highlighted in Figure 2. The firmware is considered a critical component.

The critical components and assemblies are:

(b) (4)

The components and assemblies control the delivery of energy to the Holder.

Bills of Material describing critical components of the Charger version White Matte and Dark Slate are provided in Appendix A3.2.3-2. This includes the firmware and all mechanical and electrical components.

3.2.3.3 Manufacturing Control

The PMI source inspection aims at:

- Verifying that the products (b) (4) comply with the specifications and requirements set by PMI.
- Determining the acceptance of the batch for final packaging process and shipment release (b) (4).

The PMI source inspection takes place at (b) (4) and is performed by PMI or an accredited third party. The THD is inspected in order to approve its release for distribution. The inspection activities include tests performed in order to ensure functionality according to specifications.

(b) (4) as a supplier to PMI provides a Certificate of Conformance (CoC) to PMI with each (b) (4) (see Appendix 3.2.3-3). (b) (4) CoC states conformity to:

- PMI specifications (Visual Inspection, Heating Blade and firmware testing) and quality requirements
- Application of PMI validated test methods

The CoC is the evidence that the shipment batch has been checked, passed all acceptance criteria defined and was released.

Quality control performed by PMI starts with sampling completed goods according to an established sampling plan. The samples are inspected according to an established inspection protocol, which include steps, conditions, setups, measurements and tests to be carried out. In addition, the protocol describes the documents, templates and systems to be used during the incoming inspection. For the purpose of batch release, no samples are retained at PMI upon completion of the inspection protocol.

(b) (4).

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3.2.3.4 Design Verification

The purpose of the design verification program is to confirm that the THD conforms to the Functional Design Specification (FDS) set. PMI has structured the Design Verification (DV) activities in successive steps (see Figure 1).

(b) (4)



Figure 4 Design Verification – Activities Sequence

3.2.3.4.1 Functional Design Specification

The FDS provides a list and description of requirements for the Tobacco Heating System. The set of Functional Requirements (FR) are listed and numbered with a unique identification number for all FDS. The Device FDS (Holder and Charger) is provided in Appendix A3.1-2.

3.2.3.4.2 Design Verification Plan

(b) (4)

3.2.3.4.3 Design Test Specifications

(b) (4)

3.2.3.4.4 Design Test Reports

(b) (4)

.

3.2.3.4.5 Design Verification Report

(b) (4)

(see Appendix A3.2.1-5).

3.2.3.4.6 Overview – Design Verification – Activities by Categories

PMI has structured the Design Verification (DV) activities in various categories (see Figure 5)

The DV includes the verification activities for the Holder (also referred to as Tobacco Stick Holder) and the Charger (also referred to as Main Unit, MU). The DV of the Tobacco Stick (Section 3.2.2) and Device accessories were considered out of scope for the purpose of this Section.

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(b) (4)



RTD = Resistance To Draw

Figure 5 Design Verification – Activities by Functional Test Categories

Codes for items which had to undergo a full verification process are given in Table 2. (b) (4)

Table 2 Item Codes of Device under Tests (DUT)

DUT	Description	Item Code
Holder V2.4 White Matte	Platform 1 – ZRH/THD 2.4/ZRH Holder firmware - 1.1.1 (v2.4)/C28/FPD 4.4 Tobacco Stick Holder (THD v2.4) - White Matte	DV.000180
Holder V2.4 Dark Slate	Platform 1 – ZRH/THD 2.4/ZRH Holder firmware - 1.1.1 (v2.4)/C28/FPD 4.4 Tobacco Stick Holder (THD v2.4) - Dark Slate	DV.000174
MU V2.4 White Matte	Main Unit Platform 1 – ZRH/FPD 4.2 National Launch / White Matte	DAC.000028
MU V2.4 Dark Slate	Main Unit Platform 1 – ZRH/FPD 4.2 National Launch / Dark Slate	DAC.000027

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3.2.3.5 Packaging

THD is packaged in a customized cardboard box, consisting of an outer board, which also comprises the outer labeling, polymer blisters and an inner cardboard with custom cutouts to hold the Device securely during transportation and storage. A User Guide is included (see Appendix A3.4.1).

THD packaging includes a label with serial number and item number.

3.2.3.6 Compliance with Standards

THD is designed and manufactured in accordance with all appropriate and applicable legal and regulatory requirements in the proposed market. External standards are used when available and applicable for the product category and all system / sub-systems listed below (see Table 3), have been third-party tested according to the following regulatory compliance standards.

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Table 3 Use of Standards

Product	Model	Standard	Version	Description
Pocket Charger - Battery	A1502	IEC 62133	2012	Safety of secondary cells and batteries
		UL 1642	-	Lithium batteries
		UN38.3	Rev 5	Transportation tests for lithium metal and lithium ion batteries
Holder - Battery	A1402	IEC 62133	2012	Safety of secondary cells and batteries
		UL 1642	-	Lithium batteries
		UN38.3	Rev 5	Transportation tests for lithium metal and lithium ion batteries
AC Power Adaptor	S21A22	IEC 61558-1	2005 + A1:2009	Safety of power transformers, power supplies, reactors and similar products for supply voltages up to 1100 V
		IEC 61558-2-16	2009 + A1:2013	Particular requirements and tests for switch mode power supply units and transformers for switch mode power supply units
		UL 1310	Edition 6	Class 2 power units
		CAN/CSA C22.2 No 223-15	2015	Power supplies with extra-low-voltage class 2 outputs
		FCC Rules (Title 47 Code of Federal Regulations) Part 15; Subpart B	2014	Radio frequency devices - Unintentional radiators
		US DOE: 10 CFR Parts 429 and 430	-	Office of energy efficiency and renewable energy - international efficiency marking protocol for external power supplies
		NRCAN	A11:2011	Energy efficiency regulations for external power supplies level VI
		ICES-003	Issue 6	Information Technology Equipment (Including Digital Apparatus) — Limits and Methods of Measurement

(table continues)

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Product	Model	Standard	Version	Description
Tobacco Heating Device	2.4	IEC 60335-1	2010	Safety of household & similar devices
		EN 62233	2008	Electromagnetic fields and human exposure
		EN 55014-1	2006 + A2:2011	Electromagnetic compatibility - emissions
		EN 55014-2	2015	Electromagnetic compatibility - immunity
		EN 61000-3-2	2014	Electromagnetic compatibility - harmonic current emissions
		EN 61000-3-3	2013	Electromagnetic compatibility - voltage changes, fluctuations and flicker
		IEC 61000-3-2	2014	Electromagnetic compatibility - harmonic current emissions
		IEC 61000-3-3	2013	Electromagnetic compatibility - voltage changes, fluctuations and flicker
		EN 61000-6-1	2007	Electromagnetic compatibility - Part 6-1: Generic standards - Immunity for residential, commercial and light-industrial environments
		EN 61000-6-3	2007 + A1:2011	Interpretation sheet 1 to amendment 1 - Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for residential, commercial and light-industrial environments
		CISPR 14-1	2005 + A2:2011	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission
		CISPR 14-2	2015	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus – Part 2: Immunity

(table continues)

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Product	Model	Standard	Version	Description
		FCC Rules (Title 47 Code of Federal Regulations) Part 15; Subpart B	2014	Radio frequency devices - Unintentional radiators
		ICES-003	Issue 6	Information Technology Equipment (Including Digital Apparatus) — Limits and Methods of Measurement

Additionally THD 2.4 is in full compliance with the following European Directives:

- 2014/35/EU Low Voltage Directive
- 2014/30/EU Electromagnetic Compatibility Directive
- 2011/65/EU Restriction of Hazardous Substances
- 2006/66/EC Batteries and Battery Waste Directive
- 2012/19/EU Waste Electrical & Electronic Equipment Directive

The applicable certificates listed in Table 3 and above are available in Appendix A3.2.3-4.

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