

Encl. A1

K 97 0886

**Heraeus**  
MED

blue 80 Hospital, K954169

APR 16 1997

Summary

**Date:** 20. December 1995

**Address:** HERAEUS MED GmbH  
Heraeusstraße 12 - 14  
63450 Hanau

**Contact person:** Mark Schulz

**Establishment Registration Number:** 8010602

**Proprietary Name:** HANAULUX blue 30 & 80

**Version:** HANAULUX blue 80 Hospital

**Common Name:** Examination Light and Surgical Light

**Device Classification:** Regulatory Class II, 79FSY

**Compliance with Standards:** UL 2001 Safety of Medical Electrical Equipment  
IEC 601-1 Safety of Medical Electrical Equipment  
UL 153 Portable Electric Lamps

**Substantial equivalence:** This product is similar in function to the existing surgical lighting program HANAULUX "City" series and HANAULUX 2000.

Encl. A2

**Heraeus**  
MED**blue 80 Hospital, K954169****Description of Device:**

Hanaulux blue 80 Hospital is an Examination and Surgical Stand Light. The Hanaulux<sup>®</sup> blue 80 Hospital is principally the same as the Hanaulux<sup>®</sup> blue 80 Stand in design, material and function. The only difference is that the Hanaulux<sup>®</sup> blue 80 Hospital is equipped with an additional battery supply unit fitted to the stand pole and stand foot. The batteries will be charged up while the Hanaulux<sup>®</sup> blue 80 Hospital is connected to a mains supply. In case of a failure of the mains supply the light will be automatically switched over to the battery supply.

All used plastics are molded of UL Recognized Component material.

All internal wiring is either Listed fixture wire or Recognized Component appliance wiring material.

The maximum of UV Irradiance is lower than  $6 \text{ W} / \text{m}^2$ .

Hanaulux<sup>®</sup> blue 80 Hospital is intended to be installed in accordance with the National Electrical Code.

March 24, 1997

Mark Schulz

Development Engineer  
Electric Construction