

## DECLARATION OF CONFORMITY According to ISO/IEC/<u>EN17050-1</u>



## Declares with sole responsibility of the manufacturer, that the product

Product Common Name : AUTOMATED EXTERNAL DEFIBRILLATOR

Reference : HeartOn A15®

Product Model Name(s) : HeartOn A15® (8 action icon of HeartOn A15)

HeartOn A15-G4® (4 action icon of HeartOn A15)

Further description of the device and modules are given in instruction manual.

Classification / Rule : IIb / Rule 9

GMDN : 48049 (Non-rechargeable professional semi-

automated external defibrillator),

47910 (Non-rechargeable public semi-automated

external defibrillator)

Conformity Assessment Route : Annex II excl. section 4

## **Supplementary Information**

The above product(s)

complies (comply) with the applicable requirements of Medical Device Directive, 93/42/EEC as amended by 2007/47/EC of 21 September 2007 and bear(s) the CE-marking accordingly.

is (are) subject to the procedure set out in Annex II excl. section 4 of Directive 93/42/EEC as amended by 2007/47/EC under the supervision of