



DECLARATION OF EC CONFORMITY

WE:

Name of Manufacturer:
SOLAR

Limited Liability Company

EU Representative:
VARIA Ltd.

UKRAINE, 36014 Poltava, Petra Doroshenka str. 57
PRZEDSIĘBIORSTWO Innowacyjno- Handlowe

POLAND, 60-473 Poznan, Biecka str. 10

Hereby declare, that the product:

Name of product:

Recording Thermal Papers for medical devices

(ECG, EEG, CTG, videoprinters, spirometers, autoclaves, laboratory printers, defibrillators and other medical devices in which the recording thermal papers are used)

Product code:

aa x bb (aa x bb x cc) It depends on dimension and format type

Classification

(per rule 1, Annex IX, 93/42/EEC):

Device of class "I"

conforms to the MDD 93/42/EEC Council Directives

Applied harmonized standards, national

standards or other normative documents: EN ISO 9001:2009, PN-EN ISO 9001:2009, EN 980:2008, PN-EN 980: 2008, EN 1041:2008, PN-EN 1041:20120

Conformity assessment procedure: Annex VII point 3 of MDD 93/42/EEC Directive

Technical files at competent authority disposal

Poltava, 30-05-2019



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