

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Medset Medizintechnik GmbH

Curslacke Neuer Deich 66, 21029 Hamburg, Germany

Certified location:

Curslacke Neuer Deich 66, 21029 Hamburg, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50271-Z6-00, the decision dated 2019-12-02 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-12-02 to 2024-05-26

Registration No.: 50271-16-06



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-12-02
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50271-16-06

Valid from 2019-12-02 to 2024-05-26

Revision status of the annex: 1 dated 2021-05-22

Devices/device categories included in the certificate:

Class II a:

- MD1111
 - Software for 32-Bit Systems
 - Long-term ECG PADSY-Holter 4.4
 - Rest ECG PADSY-ECG 4.4
 - Stress ECG PADSY-Ergo 2.14
 - Spirometry PADSY-Spiro 1.2
 - Ambulatory Blood Pressure Monitoring (ABPM) PADSY-RR 1.11
 - Software for 64-Bit Systems
 - Long-term ECG PADSY Holter 4.5
 - Rest ECG PADSY ECG 4.5
 - Stress ECG PADSY Ergo 2.15
 - Spirometry PADSY Spiro 1.3
 - Ambulatory Blood Pressure Monitoring (ABPM) PADSY RR 1.12
- MD1302
 - Hardware for
 - Ambulatory Blood Pressure Monitoring (ABPM) Recorder SCANLIGHT
 - Spirometry Sensor Spirosound



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