

EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: DE-MF-000005715)

Dr. Fenyves und Gut Deutschland GmbH

Daimlerstraße 23
72414 Rangendingen
Germany

has implemented and applies a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils the following requirements:

Annex IX - Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate consists of 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-12-18	Registration No.	D1083500016
Valid until:	2028-12-17	Evaluation Report No.	P22-01447-247509

Stuttgart, 2023-12-18



Head of Notified Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zfg.de

BS-MDR-098

Devices:

Product:
Sonata Patient recorder
SleepDoc Porti 10 PSG
VitalNight PSG

Risk class: IIa

Product:
Sonata Neuro module

Risk class: IIa

Product:
Scala
SleepDoc Porti 10 PG

Risk class: IIa

Product:
SleepDoc Porti 7
VitalNight Plus
MiniScreen Plus

Risk class: IIa

Product:
SleepDoc Porti 8
VitalNight Pro
MiniScreen Pro

Risk class: IIa

Product:
SleepDoc Porti 9
Samoa
VitalNight PG
Samoa lite
PolyX

Risk class: IIa
