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: CH-MF-000008529)

Sentec AG

Kantonsstrasse 14
7302 Landquart
Switzerland

EU Authorized Representative: Sentec GmbH, Carl-Hopp-Str. 19A, 18069 Rostock, Germany (SRN: DE-AR-000007618)

has implemented and applies a quality management system in accordance with Annex IX, Chapter I 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)

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:	2021-12-17	Registration No.	D1419900009
Valid until:	2026-12-16	Evaluation Report No.	202287

Stuttgart, 2021-12-17

Head of Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Product: LuMon™ Monitor

Risk class: IIa – not implantable
Basic-UDI-DI: ++EIT1P070287AF2

Product: SensorBeltConnector

Risk class: IIa - not implantable
Basic-UDI-DI: ++EIT1P070287BF4

Product: LuMon™ Connector

Risk class: IIa - not implantable
Basic-UDI-DI: ++EIT1P070287CF6

Product: LuMon™ Module

Risk class: IIa - not implantable
Basic-UDI-DI: ++EIT1P070287DF8
