For electronic distribution only
Nur zur elektronischen Verbreitung

EU Quality Management System Certificate

We hereby certify the company

Sentec AG
Kantonsstrasse 14
7302 Landquart
Switzerland

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets 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 from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2026-03-20	Registration No.	D1419900013
Valid until	2026-12-16	Report No.	P25-00585-357941

Stuttgart, 2026-03-20

Notified Body

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

EU Authorized Representative:

SenTec GmbH
Carl-Hopp-Strasse 19
18069 Rostock
Germany
DE-AR-000007618

Devices:

LuMon™ Connector

Risk class: IIa

LuMon™ Monitor

Risk class: IIa

The certificate is based on the previous certificate

D1419900009 (2021-12-17)

with the following changes to D1419900009:
Restricted by the products: SensorBeltConnector and LuMon™ Module