

EU Certificate of Conformity (MDR)

Berlin, 05/05/2026
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The organization

livetec Ingenieurbüro GmbH

Marie-Curie-Str. 8, 79539 Lörrach, Germany

Certified to have implemented and applied a quality management system in accordance with Regulation (EU) 2017/745, Annex IX, Chapters I and III for the conformity assessment of the listed products or product categories.

The audit, report no B-23-143-S-EZ, has provided evidence that the requirements of Annex IX, Chapter I of Regulation (EU) 2017/745 are met. The manufacturer is subject to surveillance in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745. The holder is authorized to use this certificate as part of his manufacturer's declaration of conformity.

The CE marking of the notified body, notified under No. **0633**, may be affixed if the applicable EU regulation is complied with.

The validity of this certificate is linked to the maintenance of certification in accordance with EN ISO 13485 by Berlin Cert GmbH.

Valid from 05/05/2026 to 18/02/2031.



Peter Diesing

Authorized representative, 05/05/2026



The scope of validity of certificate no. Z-23-143-S-E-N1 for the organization

livetec Ingenieurbüro GmbH

covers the following products:

Product / Product category	Basic UDI-DI	Risk class
auxil ECG	426058522ECG-RecorderB8	Ila
Cardioline ECG	426058522ECG-RecorderB8	Ila
dpv-ritmo III	426058522ECG-RecorderB8	Ila
ECG Time-S	426058522ECG-RecorderB8	Ila
kECG-1	426058522ECG-RecorderB8	Ila
kECG-3	426058522ECG-RecorderB8	Ila
liveECG-V2	426058522ECG-RecorderB8	Ila
net_ECG SDX	426058522ECG-RecorderB8	Ila
smart ECG	426058522ECG-RecorderB8	Ila
VIREOFLEX3	426058522ECG-RecorderB8	Ila

Investigations and tests performed:

<TDAR> dated <17.02.2026>

<CEAR> dated <26.01.2026>

Restrictions:

Replacement note:

This certificate replaces certificate < Z-23-143-S-IX > dated <19.02.2026>

Reason for change: <Addition of another product: VIREOFLEX>



Peter Dising

Authorized representative, 05/05/2026