EU Quality Management System Certificate

We hereby certify the company

AIT Austrian Institute of Technology GmbH
Giefinggasse 4
1210 Wien
Austria

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	2024-07-09	Registration No.	D4009100003
Valid until	2027-12-04	Report No.	P24-00975-305489

Stuttgart, 2024-07-09

Notified Body

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

Devices:

encevis

Intended purpose: Software for the review and the automatic analysis of electroencephalographic data.

Risk class: IIb

UNEEG™ EpiSight Analyzer

Risk class: IIa

KITMed

Risk class: IIa

ARCSolver

Risk class: IIa

KITGuideMe

Risk class: IIa

The certificate is based on the previous certificate

D4009100001 (2022-12-05)
D4009100002 (2024-03-28)

with the following changes to D4009100002:
Extension by the product: KITGuideMe