XUND Solutions GmbH
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SRN: AT-MF-000014461

Declaration of Conformity

Product details:

Product name **XUND v1**
Software version **v1.31.1**
Basic UDI-DI **1918000298XUND01HA** Classification according 2017/745 **Class IIa ; according to rule 11**

Assessment details:

Notified body **TÜV SÜD Product Service GmbH (0123)** Route of directive regulation 2017/745 **according to Annex IX**
Certificates **G10 111420 0001**

Used standards:

Harmonized standards and other standards

Standard	No.	Part	Date / Release Title
ISO	20417	n/a	2021 Information supplied by the manufacturer of medical devices
EN ISO	13485	n/a	2016+A11/2021 Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO	14971	n/a	2019+A11/2021 Medical devices - Application of risk management to medical devices
EN ISO	15223	1	2016 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN IEC	62304	n/a	IEC 62304:2006 + A1:2015); German Version EN 62304:2006 + Cor.:2008 + A1:2015 Medical device software - Software life-cycle processes

			DRAFT: IEC/DIS 62304:2019(E)
IEC	62366	1	2015 Medical devices - Part 1: Application of usability engineering to medical devices
IEC	82304	1	2016 Health software — Part 1: General requirements for product safety

EEC MEDDEV 2.7/1 rev. 4 4 2016 CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC

We declare under sole responsibility that the products described above as delivered are in compliance with the regulation 2017/745. The products are CE marked.

CE 0123

Vienna, 30.01.2025

Signed by:
Tamas Petrovics
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Tamás Petrovics
Co-Founder & CEO