XUND Solutions GmbH
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SRN: AT-MF-000014461

Declaration of Conformity

Product details:

Product name	**XUND v1**
Product version	**v1.39.1**
Basic UDI-DI	**918000298XUND01HA**
Classification according to **MDR (EU) 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 DRAFT: IEC/DIS 62304:2019(E)	Medical device software - Software life-cycle processes
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, 24.07.2025

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