

XUND Solutions GmbH

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 SRN: AT-MF-000014461



Declaration of Conformity

Product details:

Product name	XUND v1
Software version	v1.18
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 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, 18.07.2023

DocuSigned by:

Tamas Petrovics

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Tamás Petrovics
Co-Founder & CEO