

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I,
Section 2 and 3 and Chapter III



Registration No.: HZ 1714954-1

Manufacturer: **Hope Care S.A.**
Rua da Criatividade, Parque Tecnológico de Óbidos, Ed. Centrais
2510-216 Óbidos
Portugal

EUDAMED Single
Registration No.: PT-MF-000002817

Products: Products of class IIb:
Z129082 - VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION
AND THERAPEUTIC INTERVENTIONS
VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION
AND THERAPEUTIC INTERVENTIONS - SOFTWARE ASSESSORIES

Authorised representative(s): Not applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-10-27

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 92622727 030
Effective date: 2023-10-27
Expiry date: 2028-10-26
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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.