

EU Certificate

Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapters I and III

Registration No.: HZ 1419035-1
Manufacturer: RAPID Biomedical GmbH
Kettelerstr. 3-11
97222 Rimpfing
Germany

EUDAMED Single
Registration No.: DE-MF-000008285

Products: Products of class IIa:

Z1105 - MAGNETIC RESONANCE IMAGING (MRI)
INSTRUMENTS

Authorized representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
1	Re-certification Replaces certificate HZ 1419035-1 Rev. 0 issued 2021-12-13	2026-02-09

The Notified Body hereby declares that the requirements of Annex IX, Chapter I 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.: 1201515-10
Effective date: 2026-02-12
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This certificate can be validated on <https://www.certipedia.com>

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.



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