EU Certificate

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

Registration No.: HZ 1703016-1

Manufacturer: SiCAT GmbH & Co. KG
Friesdorfer Str. 131-135
53175 Bonn
Germany

EUDAMED Single Registration No.: DE-MF-000005604

Products:

Products of class IIa:

Z110603 - PICTURE ARCHIVING AND COMMUNICATION SYSTEMS

Authorized representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
2	Re-certification. Replaces certificate HZ 1703016-1 rev. 1 issued 2022-06-09	2026-04-28

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.: 1213832-100

Effective date: 2026-06-26

Expiry date: 2031-06-25

Issue date: 2026-04-28

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This certificate can be validated on https://www.certipedia.com

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