

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 1992126-1

Manufacturer: UAB Softneta
Baršausko str. 59B
Kaunas LT-51423
Lithuania

EUDAMED Single
Registration No.: Not available

Products: Class IIb:
Z119082 - VARIOUS BIOIMAGING AND RADIOTHERAPY INSTRUMENTS –
SOFTWARE

Authorised
representative(s): N/A

Certificate history

Revision:	Description:	Issue date:
1	Initial	2021-06-02

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.: 84947045-50

Effective date: 2021-06-02

Expiry date: 2025-10-22

Issue date: 2021-06-02



Maciej Ściera
Maciej Ściera
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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