

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 1554225-1
Manufacturer: GRENA Ltd.
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

EUDAMED Single
Registration No.: IE-AR-000001156.

Products: Products of class I, reusable surgical instruments:

L070801018001 Forceps for the application and removal
of vascular clips, reusable
- Reusable Ligating Clip Appliers
- Reusable Ligating Clip Remover

L1202 Laparoscopic and thoracoscopic surgery scissors,
reusable
- Reusable Articulating Endoscopic Scissors

The scope of certification is limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for re-processing of class I reusable surgical instruments.

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.: 84973025-30
Effective date: 2024-04-29
Expiry date: 2026-11-22
Issue date: 2024-04-29

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


Daniel Świątko
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.



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Authorized representative(s): MDML INTL Ltd.
10 McCurtain Hill, Clonakilty
Co. Cork., P85 K230
Republic of Ireland

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2021-11-23
1	Scope change Added reference to SRN and EU Representative Update of expiry date	2024-04-29

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