EU Certificate

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

TÜVRheinland®

Registration No.: HZ 1620952-1

Manufacturer: **STORZ MEDICAL AG**
Lohstampfestr. 8
8274 Tägerwilen
Switzerland

EUDAMED Single Registration No.: CH-MF-000014374

Products: Product class IIb:

Z121601 - EXTRACORPOREAL LITHOTRIPSY INSTRUMENTS
Z12160101 - EXTRACORPOREAL LITHOTRIPTERS
Extracorporeal devices for shock-wave therapy (ESWL, ESWT)

Authorised representative(s): Storz Medical Deutschland
Victor-Goerttler-Strasse 11
07745 Jena
Germany

Certificate history		
Revision:	Description:	Issue date:
0	First issue	2023-06-15
---	---	---

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.: 1093262-40

Effective date: 2023-06-15

Expiry date: 2028-06-14

Issue date: 2023-06-15

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Roland Gruber
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.