

# 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 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



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.