

# EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

## MDR 809629 R000

**Manufacturer:** Key Surgical LLC

**Address:**

8101 Wallace Road  
Eden Prairie  
Minnesota  
55344  
USA

**Single Registration Number:** US-MF-000029021

**EU Authorised Representative:** MDSS GmbH

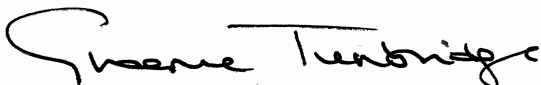
**Address:**

Schiffgraben 41  
D-30175 Hannover  
Germany

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2026-03-17**

Current Issue Date: **2026-03-17**

Starting Validity Date: **2026-03-17**

Expiry Date: **2031-03-16**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

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### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Electrosurgery Devices, Single-Use - Other	Class IIa
Electrodes Cleaning Sponges	Class Is
Cannulas and Tips for Aspiration and Irrigation, Single-Use	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.



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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
Current	30180776	Issued



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