

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2419940-1

Organization: SOF MEDICA SRL
Sos. NICOLAE TITULESCU, Nr. 3, Bloc A1, Etaj 6, Ap. 46
011131 București
Romania

Scope: Distribution, installation and servicing of active surgical devices used in robotic-assisted surgery, surgical care, cardiovascular care, endoscopy and critical care. Distribution of related spare parts. Provision including translation of the information supplied by manufacturers, clinical support and training for related medical devices of professional users

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84956180-60
Effective date: 2022-04-21
Expiry date: 2025-02-09
Issue date: 2022-04-21



TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Jarosław Pyclik
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Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	SOF MEDICA SRL Sos. NICOLAE TITULESCU, Nr. 3 Bloc A1, Etaj 6, Ap. 46 011131 București Romania	Administration
/02	SOF MEDICA SRL Calea Bucurestilor 87-91 075100 Otopeni, Ilfov Romania	Distribution, installation and servicing of active surgical devices used in robotic-assisted surgery, surgical care, cardiovascular care, endoscopy and critical care. Distribution of related spare parts. Provision including translation of the information supplied by manufacturers, clinical support and training for related medical devices of professional users

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