

# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 2419940-1

Certificate Holder: SOFMEDICA S.A.  
Sos. NICOLAE TITULESCU, Nr. 3, Bloc A1, Etaj 6, Ap. 46  
011131 București  
Romania

Scope: Distribution, installation and servicing of medical devices used in robotic-assisted surgery, surgical care, cardiovascular care, endoscopy, critical care and pulmonology 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.: 84968959-20

Effective date: 2024-02-16

Expiry date: 2025-02-09

Issue date: 2024-02-16

Replaces certificate SX 2419940-1 issued 2023-02-24



Jarosław Pyclik  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	SOFMEDICA S.A. Sos. NICOLAE TITULESCU, Nr. 3, Bloc A1, Etaj 6, Ap. 46 011131 București Romania	Administration.
/02	SOFMEDICA S.A. Calea Bucurestilor 87- 91 075100 Otopeni, Ilfov Romania	Distribution, installation and servicing of medical devices used in robotic-assisted surgery, surgical care, cardiovascular care, endoscopy, critical care and pulmonology 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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