

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2419940-1

Certificate Holder: Sof Medica 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 robot-assisted surgery, surgical care, cardiovascular care, endoscopy, critical care, pulmonology, neurology, and interventional cardiology, as well as the distribution of related spare parts.
Provision of translation services for manufacturer-supplied information, along with clinical support and training for professional users of related medical devices. Changes to the outer packaging of medical devices, including a change in pack size.

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.: 84979071-20

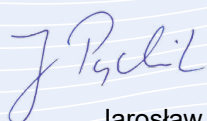
Effective date: 2025-02-10

Expiry date: 2028-02-09

Issue date: 2025-02-10

Replaces certificate SX 2419940-1 issued 2024-02-16

This certificate can be validated on <https://www.certipedia.com>


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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	SOF MEDICA S.A. Sos. NICOLAE TITULESCU, Nr. 3, Bloc A1, Etaj 6, Ap. 46 011131 București Romania	Administration.
/02	SOF MEDICA S.A. Calea Bucurestilor 87-91 075100 Otopeni, Ilfov Romania	Distribution, installation, and servicing of medical devices used in robot-assisted surgery, surgical care, cardiovascular care, endoscopy, critical care, pulmonology, and neurology, as well as the distribution of related spare parts. Provision of translation services for manufacturer-supplied information, along with clinical support and training for professional users of related medical devices. Changes to the outer packaging of medical devices, including a change in pack size.
/03	SOF MEDICA S.A. 131 Kifissias Avenue 15124 Maroussi Greece	Distribution, installation, and servicing of medical devices used in robot-assisted surgery, surgical care, cardiovascular care, endoscopy, critical care, pulmonology, neurology, and interventional cardiology, as well as the distribution of related spare parts. Provision of translation services for manufacturer-supplied information, along with clinical support and training for professional users of related medical devices. Changes to the outer packaging of medical devices, including a change in pack size.
/04	SOF MEDICA S.A. 119 Kifissias Avenue 15124 Maroussi Greece	Distribution of medical devices used in robot-assisted surgery, surgical care, cardiovascular care, pulmonology, neurology, and interventional cardiology, as well as the distribution of related spare parts. Provision of translation services for manufacturer-supplied information. Changes to the outer packaging of medical devices, including a change in pack size.

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