

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 1224966-1
Certificate Holder: TEHNO BIONIC S.R.L.
Agriciculturii nr 55
120057 Buzau, Judetul Buzau
Romania
Scope: Design, manufacture and service of saline therapy equipment

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.: 84980182-20
Effective date: 2025-03-01
Expiry date: 2028-02-28
Issue date: 2025-02-28
Replaces certificate SX 1224966-1 issued 2024-11-17

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	TEHNO BIONIC S.R.L. Agriculturii nr 55 120057 Buzau, Judetul Buzau Romania	Design, manufacture and service of saline therapy equipment
/02	TEHNO BIONIC S.R.L. Sat Mierea 101 127679 Comuna Vernesti, Judetul Buzau Romania	Manufacture of saline therapy equipment

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