EU Quality Management Certificate

This is to certify that the company

NOVATECH SA

Z.I. Athélia III
1058, Voie Antiope
13705 La Ciotat CEDEX
France

SRN: FR-MF-000001658

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	501581 MDR2017Q
Certificate ID	1000317364
Effective date	2026-07-16
Expiry date	2028-10-25
Frankfurt am Main,	2026-07-16

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sven Hoffmann
Managing Director

Annex to EU Quality Management Certificate
SRN of Manufacturer: FR-MF-000001658
Certificate ID: 1000317364

Device categories and variants covered by this certificate according to Article 52:

Device category:	**MDN 1208 – Non-active non-implantable instruments**
Product name:	Bronchoscope, rigid
Risk classification:	IIa
Basic-UDI-DI:	4063108DUTA4
Intended purpose:	The product is intended for rigid bronchoscopy

Device category:	**MDN 1208 – Non-active non-implantable instruments**
Product name:	Catheter, suction, tracheobronchial
Risk classification:	IIa
Basic-UDI-DI:	4063108SURCB
Intended purpose:	Removal of foreign bodies, liquids and tissue from the trachea and bronchi. For use with rigid bronchoscopy.

Device category:	**MDN 1104 - Non-active soft tissue and other implants**
Product name:	STERITALC F2, F4, PF3, PF3 Supplement
Risk classification:	IIb Implant
Basic-UDI-DI:	4063108STEBE
Intended purpose:	STERITALC is an insoluble mineral powder, which is applied to the pleural cavity to cause permanent pleurodesis.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	ROTEPS
Risk classification:	Ir
Basic-UDI-DI:	4063108ROTBQ
Intended purpose:	For manipulating, grasping and cutting anatomic structures and foreign bodies under rigid bronchoscopy.

Examinations and tests performed:
501581_A210874MED_01 dated 2023-01-14
501581_A210874MED_02 dated 2023-07-03
501581_A213907MED Steritalc dated 2025-07-16
501581_A213942MED ROTEPS dated 2026-03-05

Further conditions for or limitations to the validity of the certificate:
In the case of reusable surgical instruments, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing, as well as the related instructions for use.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-10-26	170782651	New certificate template
02	2024-04-03	1000167790	Addition of Steritalc
03	2025-07-31	1000257623	Addition of ROTEPS