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	1000167790
Effective date	2024-04-03
Expiry date	2028-10-25
Frankfurt am Main,	2024-04-03

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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(active medical devices)

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Head of Certification Body
(non-active medical devices)

Annex to EU Quality Management Certificate
SRN of Manufacturer: FR-MF-000001658 FR-MF-000001658
Certificate ID: 1000167790

Device categories and variants covered by this certificate:

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.

Examinations and tests performed:
501581_A210874MED_01 vom 14.01.2023
501581_A210874MED_02 vom 03.07.2023

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-10-26	170782651	New certificate template