CERTIFICATE

This is to certify that the company

NOVATECH SA

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

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
Development, production and distribution of medical devices: implants, instruments and accessories in the field of interventional pulmonology and thoracic surgery including tracheal and bronchial stents / bronchial plugs / sterile talcum powder / silicone sheetings / endoscopes / pleural trocars and surgical suction catheters.
-AUS (a), BRA, CND, JPN, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	501581 MDSAP16
Certificate unique ID	170783306
Effective date	2023-06-05
Expiry date	2026-06-04
Frankfurt am Main	2023-06-05

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

Annex to certificate
Certificate registration No.: 501581 MDSAP16
Certificate unique ID: 170783306
Effective date: 2023-06-05

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Audited site	**REPs FEI No.: site scope and country-specific requirements**
NOVATECH SA Z.I. Athélia III 1058, Voie Antiope 13705 La Ciotat CEDEX France	Development, production and distribution of medical devices: implants, instruments and accessories in the field of interventional pulmonology and thoracic surgery including tracheal and bronchial stents / bronchial plugs / sterile talcum powder / silicone sheetings / endoscopes / pleural trocars and surgical suction catheters. **AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F004979**

Annex to certificate
Certificate registration No.: 501581 MDSAP16
Certificate unique ID: 170783306
Effective date: 2023-06-05

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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821