EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

NOVATECH SA

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

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

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

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Interventional Pulmonology Products, Thoracic Surgery Products, Interdisciplinary Products according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	501581 MR2
Certificate unique ID	170773598
Effective date	2020-11-17
Expiry date	2024-05-26
Frankfurt am Main	2020-11-17

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 501581 MR2
Certificate unique ID: 170773598
Effective date: 2020-11-17

NOVATECH SA

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

Device family	Device	Class
Interventional Pulmonology Products	Respiratory Stents	IIb
	Bronchial Plugs	IIb
	Endoscopes	IIa
	Protection for Endoscopes	Is
	Endobronchial Lung Marker	IIb
Thoracic Surgery Products	Sterile Talcum Powder	IIb
	Pleura Trocars	IIa
Interdisciplinary Products	Silicone Sheeting unrestricted	IIb
	Silicone Sheeting restricted	IIa
	Surgical Suction Catheters	IIa