CERTIFICATE

EC Certificate No. 1434-MDD-228/2020

Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Respiratory Technology Corporation

11011 Brooklet Drive, Suite 300
Houston, Texas 77099 UNITED STATES

for the design, manufacture and final inspection of medical devices, class: Class IIb

Sterile active catheters, active handpiece kits, and RF surgical generators

The list of medical devices covered by this certificate is provided in the Annex No. 1

complies with requirements of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 25.05.2020 to 08.12.2022

The date of issue of the Certificate: 25.05.2020

The date of the first issue of the Certificate: 26.08.2019

CE 1434

Issued under the Contract No. MD-262/2019
Application No: 854/2019
Certificate bears the qualified signature.
Warsaw, 25/05/2020
Module H2/3/4/5

FBM-26_E_8

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.05.25 12:35:58 +02'00'

Mgr Anna Wyroba
Vice-President

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-228/2020

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Active Surgical Device	Secca Handpiece	Accessory Kit 175 5107
		8000
	Stretta Catheter	Accessory Kit 175 5580
		8800
RF Surgical Generator	RF Generator	MDRF1 Generator Kit 177-5251
		MDRF1 Generator 177-5150

CE 1434

Issued under the Contract No. 262/2019
Application No: 854/2019
Certificate bears the qualified signature.
Warsaw, 25/05/2020

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
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Mgr Anna Wyroba
Vice-President