EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

erbrich-instrumente GmbH

Eugenstraße 33
78532 Tuttlingen - Nendingen
Germany

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:

Suction and rinsing cannulas as listed in the 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.	516070 MR2
Certificate unique ID	170776143
Effective date	2021-05-20
Expiry date	2023-09-09
Frankfurt am Main	2021-05-20

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
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Device	GMDN Code	Class
Needle, Biopsy	12-734	IIa
Cannulae, Aspirating	10-566	IIa
Cannulae, Ear	10-571	IIa
Cannulae, Eye	10-573	IIa
Cannulae, Uterine	10-580	IIa
Cannulae, Nasal	16-422	IIa
Cannulae, Liposuction	17-640	IIa

erbrich®

erbrich-instrumente GmbH, Eugenstraße 33, D-78532 Tuttlingen

technik für die medizin

We hereby declare that we, in consultation with DQS, are making use of the extended transition period according VO (EU) 2023/607 until May 26, 2024.
This declaration refers to our certificate:
Suction and rinsing cannulas
Registration No. 516070MR2
ID 170776143

Tuttlingen 2023,09,18

Georg B. Erbrich
Managing Direktor
-erbrich-instrumente GmbH-

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