



EC-CERTIFICATE



(Production quality assurance)

This is to certify that the company



ELCON MEDICAL INSTRUMENTS GMBH

Dr. Karl-Storz-Straße 26 78532 Tuttlingen Germany

has implemented and maintains a quality assurance system which applies to the manufacture and final controls of the products.

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

Annex V of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Product name Class Suction cannula IIa

The manufacturer is subject to surveillance according to Annex V, Section 4. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the 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. 514464 MR5
Certificate unique ID 170739526
Effective date 2020-04-02
Expiry date 2024-05-26
Frankfurt am Main 2020-04-02

DQS Medizinprodukte GmbH

Molen

Sigrid Uhlemann Managing Director Dr. Thomas Feldmann Head of Certification Body

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