



EC-CERTIFICATE

(Production quality assurance)



This is to certify that the company

Black & Black Surgical, Inc.

5175 S. Royal Atlanta Drive
Tucker, GA, 30084
United States of America

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:

Suction and irrigation cannulas	Ila
Suction and irrigation tubes	Ila
Vitruvian Ultimate Aspirator	Ila
Vitruvian Infiltration Pump	Ila

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. 515494 MR5

Certificate unique ID 170726208

Effective date 2019-06-12

Expiry date 2023-05-18

Frankfurt am Main 2019-06-12

DQS Medizinprodukte GmbH

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