Certificate of Registration

This is to certify that the Quality Management System of

BEAR Medic Corporation

Head Office/Factory: 1361, Daigo, Daigo-machi, Kuji-gun, Ibaraki, 319-3526, Japan

applicable to

Design and development, production and distribution of sterilized medical devices (suture needles, needles, sutures, titanium plating system, distraction system, skull reconstruction system, bone connecting screws, bone connecting wires, vessel clips, and surgical instruments)

has been assessed and registered by NQA against the provisions of

BS EN ISO 13485 : 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Managing Director

Certificate No:	26701
Issue Date:	14 October 2010
Reissued:	22 November 2018
Valid Until:	22 November 2021
EAC Code:	04/19/34

UKAS MANAGEMENT SYSTEMS
015

Certificate of Registration

Appendix to Certificate Number 26701

Includes Facilities Located at:

Head Office/Factory: 1361, Daigo, Daigo-machi, Kuji-gun, Ibaraki, 319-3526, Japan	Management, Manufacture
Tokyo Branch: Yushima Bear Bldg., 2-31-24, Yushima, Bunkyo-ku, Tokyo, 113-0034, Japan	Sales, Design and development

Managing Director

Certificate No:	26701
Issue Date:	14 October 2010
Reissued:	22 November 2018
Valid Until:	22 November 2021
EAC Code:	04/19/34

UKAS MANAGEMENT SYSTEMS
015

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

BEAR Medic Corporation

Yushima BEAR Bldg.
2-31-24 Yushima
Bunkyo-ku
Tokyo 113-0034
Japan

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:

Disposable Microvascular Clip Class IIa

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.	544685 MR2
Certificate unique ID	170749778
Effective date	2020-04-15
Expiry date	2024-05-26
Frankfurt am Main	2020-04-15

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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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.