EC CERTIFICATE
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10000318097-PA-NA-NOR Rev.0.0	PRJC-508607-2014-MSL-NOR	27 May 2024

This is to certify that the quality system of:

HK Surgical, Inc.

1271 Puerta Del Sol
San Clemente, CA 92673 USA

For design, production and final product inspection/testing of:

Infiltration Pump, Aspiration Pump and accessories

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 23 May 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Sholeh Gheissar

Sholeh Gheissar
Principal Assessor

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	23-05-2021

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical Aspiration Pump	AP230-III	IIa
Surgical Infiltration Pump	KIP-II	IIa
Sterile tubing accessories	Infiltration Tubing (ITS-10, ITS-20, ITD-20, IT2X-10, CVT-10, CVT-20, CVT-10-VS) Aspiration Tubing (AT6-10, AT375)	Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
HK Surgical, Inc.	1271 Puerta Del Sol San Clemente, CA 92673 USA

EU Representative

Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate