

EC Certificate Full Quality Assurance System: Certificate BG19/871877

The management system of

Micrel Medical Devices SA

42 Konstantinoupoleos str., Koropi 19441, Athens, Greece

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Infusion pump for intravenous, intra-arterial, subcutaneous, and intraperitoneal, perineural, surgical site, epidural space, or subarachnoid space medicinal fluids infusion.

Infusion pump for parenteral nutrition.

Sterile Administration Sets.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 28 April 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 16 July 1997 and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered BG/SOF 71222127

Authorised by

SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Page 1 of 1





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