EC Certificate Full Quality Assurance System: Certificate BG19/871893

The management system of

HemCon Medical Technologies CZ s.r.o. a Division of HemCon Medical Technologies Europe Ltd.

Za Mlýnem 5, CZ 666 01, Tišnov, Czech Republic

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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 28 March 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 28 March 2018
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered BG/MED 08012

This is a multi-site certification.
Additional site details are listed on subsequent pages

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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HemCon Medical Technologies CZ s.r.o. a Division of HemCon Medical Technologies Europe Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

Non-sterile m-docTM Spray with CMC

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.

Additional facilities

720 SW Washington Street, Suite 200, Portland OR 97205, USA