

EC Declaration of Conformity

Manufacturer: Hemcon Medical Technologies CZ s.r.o.

Address: Za Mlýnem 5, 666 01 Tišnov, Czech Republic

We herewith declare under our sole responsibility that our products as listed below are in conformity with the provisions of the EC Directive 93/42/EEC, and amending directive 2007/47/EC for Medical Devices. Under the supervision of SGS Belgium NV, SGS House, Noorderlaan 87, 2030 Antwerp, Belgium.

Notified Body duly authorized by the Belgian Competent Authority to carry out such assessments, and carrying the Notified Body number 1639

All supporting documentation is retained under the premises of the manufacturer.

Hemcon Medical Technologies CZ s.r.o. agrees to develop, implement and maintain a post-production experience, monitoring processes, including the notification of reportable events under European Medical Vigilance System Guidelines.

This declaration is based on **Certification of a quality system** according to:

Directive 93/42/EEC, Annex II (excluding Section 4) and amending directive 2007/47/EC:

Certificate number: **BG19/871893**

ISO 13485:2016 Certificate number: **BG18/871634**

Product Class IIa

Generic Product Name: Non-sterile m-doc Spray with CMC
Rule 4 according to Annex IX of Medical Device Directive 93/42/EEC

Products covered by this Declaration of Conformity are:

THS013 - Seal-On CMC Spray 50ml
THS042 - HeltiQ BloodStop Spray CMC 50ml Dutch, French
THS056 - FarmaMed Spray Emostatico 50 ml
THS069 - Norgesplaster Blodstopp Spray CMC 50 ml
THS007 - Stop Saignement Spray CMC 80 ml
THS009 - Mext Bloodstop Spray CMC 80ml
THS070 - Kwizda Erste Hilfe Spray CMC 80ml
THS071 - Human Blodstopp Pulver Spray CMC 80 ml
THS072 - OC Blood Clog Spray CMC 80 ml - hemostaatti
THS075 - Work Safe Blodstopp Spray 80ml CMC

Start of CE-Marking: 14-Feb-1998 (original Certificate ID GB98/12136)

Document Version History:

Document Change	Version	Description of change
20/2018	0	First issue in new template, change of ID numbers of certificates due to internal changes of NB 0120 SGS UK/Bulgaria
04/2019	1	Correction of typo in MDD citation
08/2020	2	Update of Notified Body from SGS UK to SGS Belgium. Updated NB number from 0120 to 1639
17/2020	3	Correction of certificate number and addition of all SKUs covered by this Declaration of Conformity

Signed on behalf of Hemcon QM:

Name: Maire E. Ni Beilliu

Title: Vice President, Regulatory & Quality

Date: 12 November 2020

Signature:  Digitally signed by Maire E. Ni Beilliu
Date: 2020.11.12 12:05:56 -08'00'