EC CERTIFICATE

Number: 86793CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Flen Health N.V. Also trading as Flen Health, Flen Pharma

Blauwesteenstraat 87
2550 Kontich
Belgium

For the product category(ies)

Primary wound care polymer-based products for acute and chronic wounds and irritated skin

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:
Certification Notice 86793CN, initially dated 23 April 1998
Addendum, initially dated 16 January 2001

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 November 2023
Issued for the first time: 23 April 1998
Reissued: 1 November 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 86793CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Primary wound care polymer-based products for acute and chronic wounds and irritated skin

Issued to:

Flen Health N.V. Also trading as Flen Health, Flen Pharma
Blauwesteenstraat 87
2550 Kontich
Belgium

This certificate covers the following product(s):

Alginogel for acute and chronic wounds (class IIb)
Flaminal Forte (previously marketed as Flaminal)
FlamiZorb Forte
Flaminal Hydro
FlamiZorb Hydro

Hydroactive colloid wound gel for acute and superficial wounds (class IIa)
Flamigel
FlamiActiv
Restorgel (4 and 50 g)
Flamigel RT
FlamiActiv RT

Hydroactive colloid gel for acute irritated skin (class IIa)
Extracalm

(Flen Health N.V. also uses Flen Health, Flen Pharma N.V., Flen Pharma, Flen Health Pharma N.V. and Flen Health Pharma as trade name for the above mentioned products)

Initial date: 16 January 2001
Revision date: 5 November 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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