EC CERTIFICATE

Number: 2199352CE01

Full Quality Assurance System

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

Manufacturer:

Mylan Institutional

Coill Rua, Inverin
County Galway
Ireland

For the product category(ies)

Sterile sodium hyaluronate solutions indicated for temporary replacement of the glycosaminoglycan layer in the bladder (Cystistat®) and for viscosupplementation in treatment of osteoarthritis (Suplasyn®,GO-ON® ONE)

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 2189756CN, initially dated 25 January 2016
Addendum, initially dated 25 June 2018

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: 12 October 2023
Issued for the first time: 21 December 2016
Revised: 30 January 2019
Reissued: 12 October 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

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ADDENDUM

Belonging to certificate: 2199352CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Sterile sodium hyaluronate solutions indicated for temporary replacement of the glycosaminoglycan layer in the bladder (Cystistat®) and for viscosupplementation in treatment of osteoarthritis (Suplasyn®, GO-ON® ONE)

Issued to:

Mylan Institutional
Coill Rua, Inverin
. County Galway
Ireland

This certificate covers the following product(s):

- Cystistat® sterile sodium hyaluronate solution
- Suplasyn® sterile sodium hyaluronate solution
- Suplasyn® m.d. sterile sodium hyaluronate solution
- Suplasyn® 1-Shot sterile sodium hyaluronate solution
- GO-ON® ONE sterile sodium hyaluronate solution

Initial date: 25 June 2018
Revision date: 30 January 2019

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