EC CERTIFICATE

Number 2154875CE02

Full Quality Assurance System

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

Manufacturer:

Gynemed GmbH & Co. KG

Lubecker Straße 9
23738 Lensahn
Germany

For the product category(ies)

Cell culture media with specific supplement for use in IVF, ICSI or similar procedures for ART, containing bovine Hyaluronidase

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 2154875CN, initially dated 27 November 2012
Addendum, initially dated 17 March 2017

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 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. Additionally, DEKRA hereby declares that the manufacturer fulfils the relevant provisions as specified in Annex I of Commission Regulation 722/2012 of 8 August, 2012 concerning medical devices manufactured utilising tissue of animal origin. 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 October 2023
Issued for the first time: 17 March 2017
Reissued: 12 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

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ADDENDUM

Belonging to certificate: 2154875CE02

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Cell culture media with specific supplement for use in IVF, ICSI or similar procedures for ART, containing bovine Hyaluronidase

Issued to:

Gynemed GmbH & Co. KG
Lubecker Straße 9
23738 Lensahn
Germany

This certificate covers the following product(s):

Media with specific medium supplement (Class III)

Product name	Reference to DE certificate number
GM501 Hyaluronidase	2154875DE05

Initial date: 17 March 2017

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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