

# EC DESIGN-EXAMINATION CERTIFICATE

Number: 2154875DE05

**Directive 93/42/EEC on Medical devices, Annex II (4)**  
(Devices in Class III)

Manufacturer:

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

For the product

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

Documents, that form the basis of this certificate:

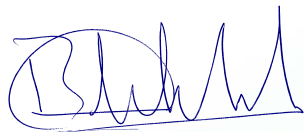
**Certification Notice 2154875CN, initially dated 27 November 2012**  
**CE Marking of Conformity 2154875CE02**  
**Addendum, initially dated 17 March 2017**

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, 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, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) 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.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and 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.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping letters.

B.T.M. Holtus  
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing initial 'J' followed by the name.

J.A. van Vugt  
Certification Manager

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

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# ADDENDUM

Belonging to certificate: 2154875DE05

1/1

## EC DESIGN-EXAMINATION MEDICAL DEVICES

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

Issued to:

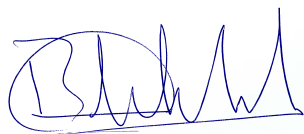
**Gynemed GmbH & Co. KG**  
**Lubecker Straße 9**  
**23738 Lensahn**  
**Germany**

This certificate covers the following product(s):

<b>Product name</b>	<b>GM501 Hyaluronidase</b>
Product code	4 HY 0001-5
	4 HY 0010

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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