

CERTIFICATE

Number: 2199147

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Gynotec B.V.

Jonckherenhof 7
6581 GC Malden
The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

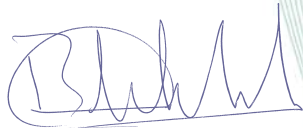
Scope:

The design and development, control of manufacture, distribution and sales of cell culture media and aspiration needles, non-active (sterile) medical devices, including medical devices incorporating medicinal substances, derivatives of human blood for assisted reproductive technologies (ART).

Certificate expiry date: 1 October 2024
Certificate effective date: 21 October 2021
Certified since: 5 October 2018

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 2199147

The management system of the organization(s) and/or location(s) of:

Gynotec B.V.

Jonckherenhof 7
6581 GC Malden
The Netherlands

Certified organization(s) and/or locations:

Different scope

Gynotec B.V.
Eendenpoelseweg 8
6581 AB Malden
The Netherlands

The design and development, control of manufacture, distribution and sales of cell culture media and aspiration needles, non-active (sterile) medical devices, including medical devices incorporating medicinal substances, derivatives of human blood for assisted reproductive technologies (ART).

Addendum expiry date: 1 October 2024
Addendum effective date: 21 October 2021