

Number: 6130288CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Genray Hangzhou Life Technology Co., Ltd.

Room 606, 6th Floor, Building 1, No. 1155 Dayuan Road

Qingshanhu Street, Lin'an District

311308 Hangzhou, Zhejiang

China

SRN ID.: TBS

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 EU- Regulation which apply to them:

0344

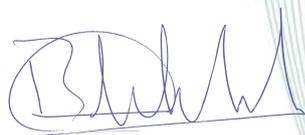
Supplement to certificate: 6116721CN

Authorized Representative: OBELIS S.A

Bd. Général Wahis, 53,1030 Brussels, Belgium

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M.A. McKenzie
Principal Certification Manager

First Issued: **5 June 2023**

Date: **5 June 2023**

Expiry date: **1 June 2028**

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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
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis (MDN 1202, class IIa)

Device Name:

- Insulin Pen Needles
- X-Safety Pen Needles

Conditions for or limitations to the validity of this certificate:

- N/A

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	5 June 2023	6116721CN02	first issue

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