



EC CERTIFICATE

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name : **Henan Simedice Biotechnologies Co., Ltd.**

Company Address : No. 28, Floor 7, Unit A, Building 1, No. 8 Guohuai Ave., Hi-tech Industries Development Zone, Zhengzhou, Henan 450001, P.R.China

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product : **Sterile, Intraocular Lens - Class IIb**

GMDN : 35658

Product Types are attached.

Certificate Number : M.2021.106.14254

Report Number : MD.3881.IB

Initial Assessment Date : 15.11.2019

Registration Date : 22.01.2021

Revision Date /No : -

Expiry Date : 27.05.2024

Handwritten signature
UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.



UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned

Address: Muflukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

EC CERTIFICATE

Number: 6085114CE01

Full Quality Assurance System

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

Manufacturer:

Henan Simedice Biotechnologies Co., Ltd.

No. 28, Floor 7, Unit A, Building 1, No. 8 Guohuai Ave.,
Hi-tech Industries Development Zone
450001 Zhengzhou, Henan
China

For the product category(ies)

Intraocular Lens for visual correction of aphakia and correction of pre-existing corneal astigmatism

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:

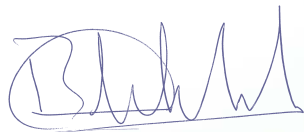
Certification Notice 6085114CN, initially dated 7 April 2021
Addendum, initially dated 7 April 2021

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: 26 May 2024

Issued for the first time: 7 April 2021

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

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 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 6085114CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Intraocular Lens for visual correction of aphakia and correction of pre-existing corneal astigmatism

Issued to:

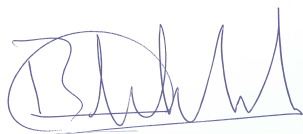
Henan Simedice Biotechnologies Co., Ltd.
No. 28, Floor 7, Unit A, Building 1, No. 8 Guohuai Ave.,
Hi-tech Industries Development Zone
450001 Zhengzhou, Henan
China

This certificate covers the following product(s):

- Toric Intraocular Lens (ST1, ST2, ST3, ST4, ST5, ST6, ST7, ST8, ST9 and ST10)

Initial date: 7 April 2021

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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Management System Certification Body No. MSCB-105

CERTIFICATE

No. 20-B-0612 Rev. 0

This is to certify that the Quality Management System of

Henan Simedice Biotechnologies Co., Ltd.

of

No. 28, Floor 7, Unit A, Building 1, No. 8 Guohuai Ave., Hi-tech Industries
Development Zone, Zhengzhou, Henan 450001, P.R.China

Company Reg. No.: 91410100MA45UNTP48

has implemented and documented a quality management system in
compliance with the requirements of the standard

ISO 13485:2016

for

Design & Development, Manufacture, Sales of Intraocular Lenses

The certificate is issued on the basis of the results mentioned in the pertinent audit report.
Validity of the certificate is conditionally limited by positive results of surveillance audits,
which the certified company committed to undergo.

This certificate can be invalid if the certificate holder does not fulfill the conditions set out in
the certification agreement.

Initial issue date: Mar. 26. 2020

Expire date: Mar. 25. 2023



Betty Kim
Head of Certification Body