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

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 sertificate 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 returnedupon 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 thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

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Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
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Digitally signed by Iarovoi Petru
Date: 2021.10.07 16:55:40 EEST
Reason: MoldSign Signature
Location: Moldova

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

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
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ADDENDUM

Belonging to certificate: 6085114CE01

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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INSTITUTE OF GLOBAL CERTIFICATION

Institute of Global Certification

IGC

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

Institute of Global Certification IGC ISO 13485 CERTIFIED

IAS ACCREDITED Management Systems Certification Body MSCB-105

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

Betty, Kim
Head of Certification Body

Rm. 501, Daeryung techno town, 638, Seobusaet-gil, Geumcheon-gu, Seoul, Republic of Korea
www.igcert.org