CE 2292

EC DECLARATION OF CONFORMITY

The Manufacturer

Name: **JETEMA Co., Ltd.**

Address: 16-25, Dongbaekjungang-ro 16beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do, Korea

Hereby declares

Product:	**Hyaluronic Acid Gel – Class III – Sterile**
Product Brand/Model/Type:	**e.p.t.q. S 500 / 300 / 100** **UNIVELO Sub-Q / Deep / Fine** **REGENOVUE Sub-Q / Deep / Fine**
GMDN Code:	**59131**
Device Classification:	**Class III (Rule 8)**
Conformity Assessment procedure:	**Council Directive 93/42/EEC Annex II (including Section 4)**
Notified Body:	UDEM (Notified Body Identification No.: 2292) Mutlukent Mahallesi 2073 Sokak No:10 Umitkoy-CANKAYA Ankara, Turkey
Certificate Numbers:	EC Design Examination M.2016.106.6812-1 EC Full Quality Assurance System M.2016.106.6812 **Valid from June 03rd 2016**

European Authorized Representative

Name:	Emergo Europe
Address:	Prinsessegracht 20 2514 AP The Hague The Netherlands

- meets the essential requirements stated in Annex I of the Council Directive 93/42/EEC as amended by 2007/47/EC.
- is put on the market with the CE Mark, according to the Council Directive 93/42/EEC as amended by 2007/47/EC.
- applicable harmonized standards applied to this device (Please refer to ***Annex 1***).
- Jetema is certified to EN ISO 13485:2012 under the Notified body: LL-C (Certification) Czech Republic s.r.o. (Certificate No. 820073)

The manufacturer undertakes to keep, and place at the Authorities disposal, the device technical file for a period of five years from the last date of manufacture of the product.

Date: March 12th 2018

Jae Young Kim
President
For and behalf of Jetema Co., Ltd.

Annex 1. Applicable Standards

Directive / Standard / Guideline Number	Name / Title
Directive	
Council Directive 93/42/EEC	European Council Directive concerning medical devices
Standards	
EN 556-1:2001/AC:2006	Sterilization of medical devices – Requirements for medical devices to be designated “STERILE”. Requirements for terminally sterilized medical devices
EN 1041: 2008+A1:2013	Information supplied by manufacturer with medical devices
EN ISO 13485:2012/AC:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)
EN ISO 10993-9: 2009	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2009)
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2009	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2006)
EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
EN ISO 10993-13:2010	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)
EN ISO 10993-16:2010	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2010)
EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)
EN ISO 10993-18:2009	Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005)
ISO 11040-4:2015	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling
ISO 11040-7:2015	Prefilled syringes - Part 7: Packaging systems for sterilized subassembled syringes ready for filling
ISO 11040-8:2016	Prefilled syringes - Part 8: Requirements and test methods for finished prefilled syringes
EN ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
EN ISO 11138-3:2017	Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)
EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006, including Amd 1:2014)
EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006, including Amd 1:2014)

EN ISO 11737-1:2006/AC:2009	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)
EN ISO 14630:2012	Non active surgical implants – General requirements
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of Air Cleanliness (ISO 14644-1:2015)
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods (ISO 14698-1:2003)
EN ISO 14698-2:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data (ISO 14698-2:2003)
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15223-1: 2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - General requirements
EN ISO 17665-1:2006	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)
European Guidelines	
MEDDEV 2.1/1 April 1994	Definitions of “medical devices”, “accessory” and “manufacturer”
MEDDEV 2.4/1 rev.9 June 2010	Classification of medical devices
MEDDEV 2.7/1 rev.4 June 2016	Clinical evaluation: Guide for manufacturers and notified bodies
MEDDEV 2.12/1 rev.8 January 2013	Guidelines on a Medical Devices Vigilance System
MEDDEV 2.12/2 rev.2 January 2012	Post Market Clinical Follow-up studies
European Pharmacopoeia(Ph.Eur.)	European Pharmacopoeia 8th Edition
ICH guidelines Q1A	Stability Testing of New Drug Substances and Products

E C C E R T I F I C A T E

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

M.2016.106.6812-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Jetema Co., Ltd.
Company Address	: 16-25, Dongbaekjungang-ro 16beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do KOREA
Related Directives and Annex	: MDD 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Hyaluronic Acid Gel - Class III - Sterile
Product Brand/Model/Type	: e.p.t.q. S500 / 300 / 100 UNIVELO Sub-Q / Deep / Fine REGENOVUE Sub-Q / Deep / Fine
GMDN	: 59131
Certificate Number	: M.2016.106.6812
Report Number	: MD.1009.K.IB
Initial Assessment Date	: 11.11.2015
Registration Date	: 03.06.2016
Revision Date /No	: 21.02.2018/03
Expiry Date	: 02.06.2021

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 directive 93/42/EEC 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. 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 company should stop placing the product on the market. The currency of the certificate can be checked through www.udem.com. tr.

CE 2292

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EC CERTIFICATE

EC Design-Examination Certificate For Medical Devices

MDD 93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2016.106.6812 the validity of the certificate M.2016.106.6812-1 will also end.

Company Name	: Jetema Co., Ltd.
Company Address	: 16-25, Dongbaekjungang-ro 16beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do KOREA
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UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

The EC desing examination certificate refers to the above mentioned product.It certificates that the desing documentation of the product complies with Annex II,article 4 of the directive. 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 man ufacturer 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 company should stop placing the product on the market. The currency of the certificate can be checked through www.udem.com. tr.

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