BNC Biotechnology Next Challenge KOREA

#405, Daegu Techno Park Venture Factory B/D No.1,
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EC Declaration of Conformity

In accordance with EC Directive 93/42/EEC as amended

We herewith declare that the under-mentioned device, in view of its design and type of construction, meets the essential health and safety requirements of the above EC Directive 93/42/EEC amended. If the device is modified without the agreement of the under-designed, this declaration becomes invalid.

Product Name: **Cross-linked Hyaluronic Acid Dermal Filler with Lidocaine**

Trade / model name:

Trade name	Model name
VOLIFIL	CLASSIC, DEEP, Sub-Q

Relevant EC Directives: **Directive 93/42/EEC as amended**

Classification: **Class III according to Rule 8 and 13 of Annex IX of Directive 93/42/EEC as amended**

Conformity Assessment Procedure: **Annex II + point 4 of Directive 93/42/EEC as amended**

Applied Standards: **Refer to Annex I**

Manufacturers Registered Name: **BNC KOREA, Inc.**

Manufacturers Registered Address: #405, #502, #206, Daegu Techno Park Venture Factory B/D No.1, 62, Seongseogongdan-ro 11-gil, Dalseo-gu, Daegu, 42713, Korea

EC Representative Name: **JaviTech e.K.**

EC Representative Address: Sachsenhausener Str. 16, 65824 Schwalbach a. Ts., Germany
Tel: +49 6196 4021549 / E-mail: info@javitech.de

Notified Body: **3EC International a.s. (Notified Body no. : 2265)**
Hranicna 18, 821 05 Bratislava, Slovak Republic

Certificates no.: **2021-MDD/QS-023, 2021-MDD/DE-024**

Expiry date of the certificate: **May 26th, 2024**

Date of first issue: **April 26th, 2021**

Place/Date: In Daegu, Korea / on April 1, 2022

Mansub Kim
Person responsible for regulatory compliance
of BNC KOREA, Inc.

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Annex I

No.	Standard	Standard Name
1	EN ISO 13485:2016 /AC:2016	Medical devices – Quality management systems - Requirements for regulatory purposes
2	Directive 93/42/EEC as amended	Medical Device Directive
3	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
4	MEDDEV 2.12/1 rev.8	Guidelines on a Medical Devices Vigilance System
5	EN ISO 14630:2012	Non-active surgical implants – General requirements
6	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
7	EN ISO 10993-1:2020	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
8	EN ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
9	EN ISO10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
10	EN ISO 10993-6:2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
11	EN ISO10993-10:2021	Biological evaluation of medical devices -- Part 10: Tests for skin sensitization
12	EN ISO 10993-11:2018	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
13	EN ISO 10993-12:2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
14	EN 556-1:2001/AC:2006	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
15	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
16	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
17	EN ISO 11737-1:2018 / Amd 1:2021	Sterilization of health care products - Microbiological methods – Part 1: Determination of a population of microorganisms on products – Amendment 1
18	The Korean Pharmacopoeia (12th Edition)	General Tests – Sterility Test, direct inoculation method and Bacterial Endotoxins Test, kinetic-chromogenic method ** Sterility test and Bacterial endotoxins test of KP 12 is equal to that of EP 10.0.*

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19	The European Pharmacopeia (10th Edition)	Methods of analysis - Residual BDDE, 2.2.28 Gas Chromatography
20	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
21	EN ISO 11138-3:2017	Sterilization of health care products - Biological indicators – Part 3: Biological indicators for moist heat sterilization processes
22	EN ISO 14698-1:2003	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
23	EN ISO 14698-2:2003 /AC:2006	Cleanrooms and associated controlled environments – Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
24	MEDDEV 2.12/2 rev.2	Post Market Clinical Follow-up studies
25	MEDDEV 2.7/1 rev.4	Clinical evaluation: Guide for manufacturers and notified bodies
26	EN ISO 14644-1:2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration
27	EN ISO 14644-2:2015	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
28	EN ISO 14644-3:2019	Cleanrooms and associated controlled environments – Part 3: Test methods
29	EN ISO 14644-7:2004	Cleanrooms and associated controlled environments – Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
30	EN ISO 14937:2010	Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
31	EN ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
32	EN ISO 13408-1:2015	Aseptic processing of health care products – Part 1: General requirements
33	EN ISO 7886-1:2018	Sterile hypodermic syringes for single use – Part 1: Syringes for manual use