





7. EU Declaration of Conformity

No.	Reporting date	Enforcement Date	Major changes	Drafter
0	2021.09.10	2021.09.17	TCF revision according to Regulation (EU) 2017/745	Gyeongyeon Son
1	2022.08.26	2022.08.26	Standard update	Gyeongyeon Son
2	2022.11.24	2023.01.25	Added manufacturing room(#501)	Youngsim Baek
3	2022.12.27	2023.01.25	The representative address(#405) and the address of site were separated.	Youngsim Baek
4	2023.03.21	2023.03.21	EC Certificate issued.	Hanna Jo

	Department	Name (Position)	Date	Signature
Prepared by	RA Team	Hanna Jo (Assistant Manager)	2023.03.21	
Reviewed by	RA Team	Eunseon Kim (General Manager)	2023.03.21	
Approved by	Person responsible for regulatory compliance	Mansub Kim	2023.03.21	

	Technical Construction File	File No.	BNC-TCF-02-07
		Rev. No.	4
	7. EU Declaration of Conformity	Rev. Date	2023.03.21
		Page	2 / 5

EU Declaration of Conformity

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device that is covered by the present declaration is in conformity with regulation (EU) 2017/745 and specify other applicable union legislation.

Manufacturer

Name : BNC KOREA, Inc.
Registered Place of Business : #405, Daegu Techno Park Venture Factory B/D No.1, 62, Seongseogongdan-ro 11-gil, Dalseo-gu, Daegu, 42713, Republic of Korea
Manufacturing site : #201, #202, #206, #401, #404, #405, #501, #502, Daegu Techno Park Venture Factory B/D No.1, 62, Seongseogongdan-ro 11-gil, Dalseo-gu, Daegu, 42713, Republic of Korea
Single Registration Number : KR-MF-000008321

Authorized Representative

Name : JaviTech e.K.
Address : Sachsenhausener Str. 16, 65824 Schwalbach a. Ts., Germany

Device

Product Name : Anti-Adhesion Barrier Gel
Trade Name : Hibarry
Volume : 1.5 ml, 3 ml, 5 ml
Basic UDI : 880936909BNC003HC
Intended Purpose : Refer to Appendix I
Risk Class : Class III (Rule 7) according to Annex VIII of the regulation (EU) 2017/745
Applied standards : Refer to Appendix II

Notified Body


Name : 3EC International a.s.
Address : Hranicna 18, 821 05 Bratislava, Slovak Republic
Identification No. : 2265
Conformity Assessment Procedure : Annex IX of the regulation (EU) 2017/745
Identification of Certificate : 2023-MDR/QS-004, 2023-MDR/TD-004
Date of Issue of the Certificate : January 9, 2023
Expiry date of the certificate : January 9, 2028

Place/Date: In Daegu, Republic of Korea / on 2023-03-21

1

Mansub Kim

Person responsible for regulatory compliance of BNC KOREA, Inc.


	Technical Construction File	File No.	BNC-TCF-02-07
		Rev. No.	4
	7. EU Declaration of Conformity	Rev. Date	2023.03.21
		Page	3 / 5

Appendix I

Intended purpose:

Hibarry, an anti-adhesion barrier gel for use in spinal surgeries such as discectomies with a laminectomy or laminotomy.

Hibarry acts as a physical barrier to prevent adhesions from forming between the affected tissues. By inhibiting the fibrosis that can form during the healing process, post-operative pain resulting from tethered nerves can be minimized or avoided.

	Technical Construction File	File No.	BNC-TCF-02-07
		Rev. No.	4
	7. EU Declaration of Conformity	Rev. Date	2023.03.21
		Page	4 / 5

Appendix II

Common specifications		
- There is no common specification relevant to the device		
Harmonised standards		
No.	Standard	Description
1	EN ISO 13485:2016/A11:2021	Medical Devices - Quality Management System
2	REGULATION (EU) 2017/745	Medical Device Regulation
3	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
4	EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
5	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
6	EN ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
7	EN ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2010)
8	EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
9	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
10	EN ISO 10993-7:2008 /AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
11	EN ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation (ISO 10993-23:2021)
12	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.
13	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 (ISO 11737-1:2018) – Amendment 1
14	EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
15	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
16	EN ISO 11138-1:2017	Sterilization of health care products – Biological indicators – Part 1: General requirements
17	EN ISO 11138-2:2017	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
18	EN ISO 11138-3:2017	Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes
19	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
20	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
21	EN ISO 11135:2014+A1:2019	Sterilization of health care products – Ethylene oxide -Requirements for the development, validation and routine control of a sterilization process for medical devices
22	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO

7. EU Declaration of Conformity

		20417:2021)
23	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
24	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
25	EN ISO 14630:2012	Non-active surgical implants - General requirements (ISO 14630:2012)
26	EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
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 (ISO 14644-2:2015)
28	EN ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019, Corrected version 2020-06)
29	EN ISO 14644-7:2004	Cleanrooms and associated controlled environments - Part 7 Separative devices (clean air hoods, gloveboxes, isolators and mini-environments) (ISO 14644-7:2004)
30	EN ISO 14698-1:2003	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
31	EN ISO 14698-2:2003 /AC:2006	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 2: Evaluation and interpretation of biocontamination data
32	EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice
33	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
34	The European Pharmacopoeia (10th Edition)	Methods of analysis - Residual BDDE, 2.2.28 Gas Chromatography
35	CEN ISO/TR 24971	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
36	ISO/TR 20416	Medical devices - Post market surveillance for manufacturers
37	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
38	EN ISO 13408-1:2015	Aseptic processing of health care products - Part 1: General requirements
39	EN ISO 7886-1:2018	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
40	EN ISO 10993-18:2020/Amd 1:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process - Amendment 1: Determination of the uncertainty factor
41	ISO/TS 21726:2019	Biological evaluation of medical devices - Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents

Other solutions applied

No.	Standard	Description
1	MDCG 2020-5	Clinical Evaluation - Equivalence
2	MDCG 2020-6	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
3	MEDDEV 2.7/1 rev.4	Clinical evaluation: Guide for manufacturers and notified bodies
4	MEDDEV 2.12/1 rev.8	Guidelines on a Medical Devices Vigilance System
5	MEDDEV 2.12/2 rev.2	Post Market Clinical Follow-up studies