



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-MDR/TD-004

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

SRN No.: KR-MF-000008321

Name and address of the Authorized representative:

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

This EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that technical documentation of the medical device:

Anti-Adhesion Barrier Gel

(for detailed list refer to Annex I)

Intended purpose: Annex II

MD class III

Basic UDI-DI: 880936909BNC003HC

(detailed list is stated in the annex(es) if applicable)

meets the requirements of technical documentation assessment according to the Chapter II Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: N/A

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed technical documentation assessment of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the technical documentation assessment of the abovementioned medical device is stated in the MD Technical Documentation Assessment Report No. MDR049_2022 from October 26, 2022, MD Clinical Evaluation Report No. MDR049_2022 from October 26, 2022 and MD Audit Report No. SK-0685-MDR/22 from January 2, 2023. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Technical Documentation Assessment Certificate** applies only to the abovementioned medical device. For the placing on the market of the MDs which this certificate covers, the EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **January 9, 2023**

Valid until: **January 9, 2025**

First issue: **January 9, 2023**

Revision: **00**

History: **Annex III**

In Bratislava, Slovakia, January 9, 2023

Katarina Tomin Srdošová, PhD.
Director of NB2265



ANNEX I TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-MDR/TD-004

issued for the company

BNC KOREA, Inc.

Registered Place of Business: #405, Daegu Techno Park Venture Factory B/D No.1, 62,
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Republic of Korea

List of medical devices covered by the EU Technical Documentation Assessment
Certificate:

| Anti-Adhesion Barrier Gel | |
|---------------------------|--------------|
| Brand Name | Volume |
| Hibarry | 1.5, 3, 5 mL |

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Katarina Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, January 9, 2023
Valid until January 9, 2028



ANNEX II TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-MDR/TD-004

issued for the company

BNC KOREA, Inc.

Registered Place of Business: #405, Daegu Techno Park Venture Factory B/D No.1, 62,
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Intended purpose of medical devices covered by the EU Technical Documentation Assessment Certificate:

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.

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Katarina Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, January 9, 2023
Valid until January 9, 2028



ANNEX III TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2023-MDR/TD-004

issued for the company

BNC KOREA, Inc.

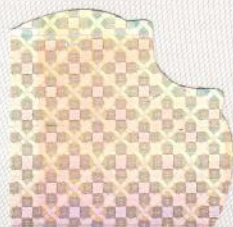
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Republic of Korea

Certificate history:

| Revision | EU TD Assessment Certificate reference | Date of issue | Application for Conformity Assessment of MD number | Description |
|----------|---|------------------|---|------------------------------------|
| 00 | 2023-MDR/TD-004 | 09. 01. 2023 | MDR049_2022 | Initially granted certification |

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, January 9, 2023
Valid until January 9, 2028