



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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-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 Quality Management System 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 quality management system of medical device:

Anti-Adhesion Barrier Gel

(for detailed list refer to Annex I)

Intended purpose: Annex II

MD class III

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

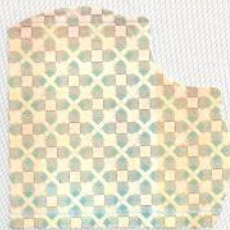
meets the requirements on quality management system according to the Chapter I Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

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 assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system 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 Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. For the placing on the market of the MDs which this certificate covers, the EU Technical Documentation Assessment 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, 2028**

First issue: **January 9, 2023**

Revision: **00**

History: **Annex III**

In Bratislava, Slovakia, January 9, 2023



3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB2265



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-004

issued for the company

BNC KOREA, Inc.

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Seongseogongdan-ro 11-gil, Dalseo-gu, Daegu, 42713, Republic of Korea

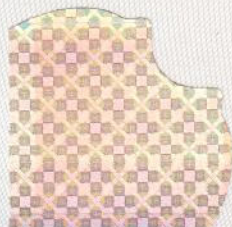
Manufacturing Site: #201, #202, #206, #401, #404, #405, #501, #502, Daegu Techno Park
Venture Factory B/D No.1, 62, Seongseogongdan-ro 11-gil, Dalseo-gu, Daegu, 42713,
Republic of Korea

List of medical devices covered by the EU Quality Management System Certificate:

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

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Notified body



Blanka Tomášová, PhD.
Director of NB2265

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



ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-004

issued for the company

BNC KOREA, Inc.

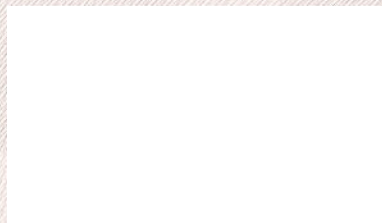
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Intended purpose of medical devices covered by the EU Quality Management System Certificate:

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.

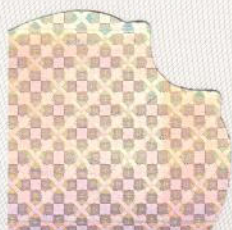
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TIKOVANÁ OSO



Katarina Tomin Srdošová, PhD.
Director of NB2265



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



ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-004

issued for the company

BNC KOREA, Inc.

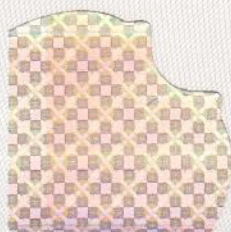
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Republic of Korea

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2023-MDR/QS-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