



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

# EC CERTIFICATE

No. 2020-MDD/QS-037/A

issued in compliance with the Council Directive 93/42/EEC as amended,  
certifies that the medical device of Class III,

**Nexsphere™**  
**UIGB100, Nexsphere-H, UIGB300, UIGB500, UIGB700**

manufactured by company

**NEXTBIOMEDICAL CO., LTD.**  
**6, Venture-ro 100 beon-gil, Yeonsu-gu, Incheon, Republic of Korea, 22013**

**is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended.**

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 310461 and the Final protocols No. 310461/2020 and 310461A/2021.

*This certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26<sup>th</sup>, 2024 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer. For the placing on the market of the above referenced models of medical devices covered by this certificate, an EC design-examination certificate according to the Directive 93/42/EEC as amended, Annex II (4) is required.



  
Dr. Katarina Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 20<sup>th</sup>, 2021  
Version A) supersedes the EC Certificate No. 2020-MDD/QS-037 issued on April 29<sup>th</sup>, 2020

Certificate history:

<b>Revision</b>	<b>Date of issue</b>	<b>Application for Conformity Assessment of MD number</b>	<b>Description</b>
0	29/04/2020	310461	First issue of the certificate
A	20/05/2021	310461A	Change of model name