



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

EC CERTIFICATE

No. 2019-MDD/QS-020/A

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll., certifies that the medical device of Class III,

Collagen Tissue Supplement
COLTRIX® CartiRegen
Model name: CL310, CL320

manufactured by company

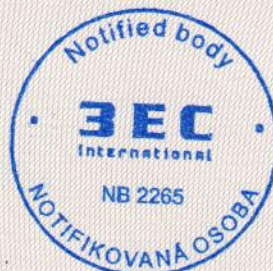
Ubiosis Co., Ltd.
SICOX Tower 817~820, 484, Dunchon-daero, Jungwon-gu, Seongnam-si,
Gyeonggi-do, 13229, Republic of Korea


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. 310288 and the Final protocol No. 310288/2019 & 310288A/2020.

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 February 21st, 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. Katarína Tomin Srdošová
Responsible to act on behalf of NB 2265

At Bratislava, on May 25th, 2020
Version A) supersedes the EC Certificate No. 2019-MDD/QS-020 issued on February 22nd, 2019