3EC International

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2024-MDR/QS-065

GENERICA spol. s r.o.

Vrbovská 39, 92101 Piešťany, Slovak Republic
SRN No.: SK-MF-000036382

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:

Lozenges
Models/Variants: see Annex I
Intended purpose: see Annex II
MD class IIa
(detailed list is stated in the annex(es) if applicable)

meets the requirements on quality management system according to the Chapter I and III of 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. MDR491_2024 from 22.11.2024, MD Clinical Evaluation Report No. MDR491_2024 from 22.11.2024 and MD Audit Report No. MDR491_2024 from 27.11.2024. 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. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **28.11.2024**
Valid until: **28.11.2029**
First issue: **28.11.2024**
Revision: **00**
History: **see Annex III**

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

3EC International a. s.
Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 28.11.2024