UKRAINE CERTIFICATION BODY OF MANAGEMENT SYSTEMS SE «KHARKOVSTANDARTMETROLOGY»



CERTIFICATE

OF QUALITY MANAGEMENT SYSTEM

Registered in the Register of Certification Authority

<u>December "24", 2021</u>

<u>Nº UA 80072.32335679.4-2021</u>

Valid until <u>December "23", 2024</u>

This certificate certifies that the quality management system regarding the design and development, production of dental products:

dental materials class I: preventive dental materials, dental waxes, dental gypsums, dental impression materials, dental polishing materials, dental aids for modeling fillings, spray oil, dental varnishes, dental aids, dental auxiliary devices, dental instruments, codes 32.50.50-10.00, 20.59.52-30.00, 20.42.18-50.00, 32.50.22-55.00, 20.59.41-79.00, 20.30.11-70.00, 20.41.20-90, 20.59.59-40.00, 32.50.11- 50.00 according to SCPS (the State Classifier of Products and Services) SC 016:2010;

dental materials class II: dental sealants, composite filling materials, endodontic filling materials, endodontic filling materials temporary, polymethacrylate dental materials, dental cements, dental temporary cements, endodontic aids, preventive dental materials, codes 32.50.50-10.00, 20.16.53 -50.00 according to SCPS (the State Classifier of Products and Services) SC 016:2010;

dental materials III class, code 32.50.50-10.00 according to SCPS (the State Classifier of Products and Services) SC 016:2010

which are manufactured by Private enterprise "Latus"

82, Tekstylna str., Kharkiv, 61010, Ukraine,

USREOU code (Unified State register of Enterprises and Organizations of Ukraine) 32335679,

in accordance with regulatory documents in force in Ukraine meet the requirements of ISO 13485:2016

"Medical devices -- Quality management system -- Requirements for regulatory purposes"

The control of conformity of the certified quality management system to the requirements of the specified standard is carried out by means of a supervisory audit, the periodicity of which is regulated by the Agreement on the use of the management system certificate.

The certificate is considered valid subject to annual confirmation: in 2022 - until December "24", 2022 and in 2023 - until December "24", 2023, which is confirmed by the Decision.

The certificate has been issued by the

Management System Certification Authority of the State Enterprise "Kharkiv Regional Scientific-Production Center for Standardization, Metrology, and Certification",

36, Myronosytska str., Kharkiv, 61002, Ukraine (accreditation attestation № 80072) based on the results of the audit of the quality management system.

Державне підприємство «Харіявський регіональний науково-виробничий центр стандартизації, метрології та General Director Код 04725906

Mikhail ZELENTSOV

Certificate validity can be verified at SE "Kharkivstandartmetrologia" by phone +380 (57) 756-38-05