EU Quality Management System Certificate CN25/00004880

The management system of

Zirdent New Material Co., Ltd.

1st & 2nd floor, Building 5, Changsha Medical device Industrial Area, No. 88, Section 1, Tengfei Road, Wangcheng Economic and Technological Development Zone, Changsha City, Hunan Province, 410200, P.R. China

SRN Number: CN-MF-000025335

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products

Class IIa device
MDN1103

Zirdent Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank
[Basic UDI DI: 697501858001K9]

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: CN/CSX/279984 - S1A 1.0 + S2A 1.1 + SUR/ESG 1.2+1.14 + TFR 1.2

Authorized representative name and address (if relevant): Eunitor GmbH; Kennedydamm 5, 40476 Düsseldorf, Germany

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

This certificate is valid from 18 July 2025 until 18 July 2030 and remains valid subject to satisfactory surveillance audits.

Recertification audit due before 18 January 2030

Issue 1. Certified since 18 July 2025

Authorised by
Virginie Siloret
Global Medical Device Certification Manager

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