

EU Quality Management System Certificate PL25/00000188

The management system of

ARKONA Laboratorium Farmakologii Stomatologicznej Grzegorz Kalbarczyk

Nasutów 99C, 21-025 Niemce, Poland
SRN Number: PL-MF-000029550

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
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 04 November 2025 until 04 November 2030 and remains valid subject to satisfactory surveillance audits.

Recertification audit due before 04 May 2030

Issue 1. Certified since 04 November 2025



Authorised by

Virginie Siloret

Global Medical Device

Certification Manager

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continued

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ARKONA Laboratorium Farmakologii Stomatologicznej Grzegorz Kalbarczyk

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

Class IIa devices:

MDN 1103

ARKON COMPOSITE (CiCC, NEXT, ONE, ESC, F2, MONOSAFE) Light cured composite dental material

(B-UDI: 590443371TF0057E)

BOND (MASTERBOND, NEW EXTRA BOND) Dental adhesive system

(B-UDI: 590443371TF01077)

CHORDS (PODWIAZKA, ПОДВЯЗКА, ПИДВ'ЯЗКА) Light cured dental fibres

(B-UDI: 590443371TF01179)

COLOURANT (COLORANT, PODBARWIA CZ) Flowable dental composites

(B-UDI: 590443371TF0037A)

COLOURFLOW (FLOW-COLOR, DEI Clever Easyflow) Flowable dental composites

(B-UDI: 590443371TF00278)

COMCORD (Włókno kompozytowe / КОМПОЗИТВОЛОКНО / ГУСЕНИЦА) Composite and fibre matrix

(B-UDI: 590443371TF0227E)

CREATE (BOSTON) Light cured composite dental material

(B-UDI: 590443371TF0067G)

SILKFLOW (FLOW-ART, DEI Clever Easyflow) Flowable dental composites

(B-UDI: 590443371TF00176)

FIBRE COMPOSITE (DEI CLEVER FIBRE COMPOSITE) Light cured composite dental material

(B-UDI: 590443371TF0237G)

MDN 1209

ETCHGEL (WYTRAWIA CZ STOMATOLOGICZNY, Etchmaster, DEI Etching Gel) Dental etching system

(B-UDI: 590443371TF0077J)

GLAZE (BOSTON GLAZURA, BOSTON GLAZE) Glaze for dental composites

(B-UDI: 590443371TF0097N)

PERIOFLUSH (PAROSIN / PERIOACTIVE) Liquid for the irrigation of periodontal pockets

(B-UDI: 590443371TF0147F)

SEALPRIM (LAK SZCZELINOWY / FISSURE SEALANT) Pit and fissure sealant

(B-UDI: 590443371TF0047C)

SHAPEDCHORDS (GASIENICA, ГУСЕНИЦЯ) Pre-formed fibre dental splints

(B-UDI: 590443371TF0127B)

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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: - PL/WAW/PL00310 - S2A 1.3+8.1 + TFR 1.21 + 1.22

Authorized representative name and address (if relevant): N/A

Previous certificate number: N/A

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

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certificate (Annex IX Chapter I and III)**

Sites

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