

The management system of

ARKONA Laboratorium Farmakologii Stomatologicznej Grzegorz Kalbarczyk

Nasutów 99 C, 21-025 Niemce, Poland

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 01 November 2010

and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered PL/WAW PL00310

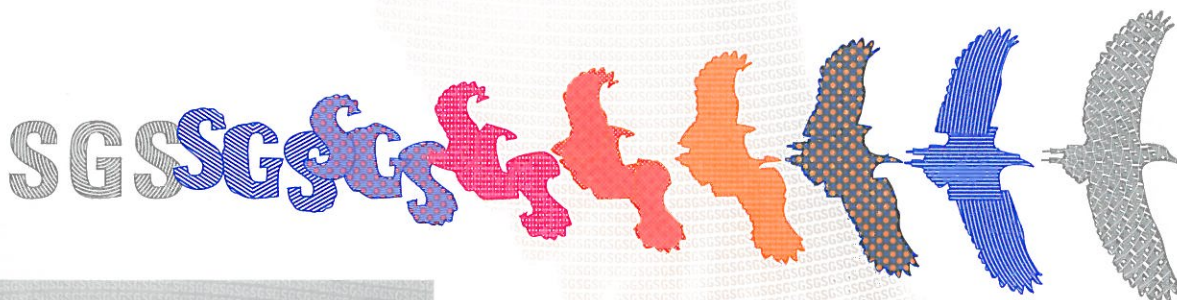
Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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ARKONA Laboratorium Farmakologii Stomatologicznej Grzegorz Kalbarczyk

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

ARKON COMPOSITE – light cured composite dental material
ciCC, NEXT, ONE, ESC – light cured composite dental material
F2 – light cured composite dental material
BOSTON, CREATE– light cured composite dental material
FIBRE COMPOSITE – light cured composite dental material
BOSTON GLAZE, GLAZE– glaze for dental composites
FLOW-ART, SILKFLOW – flowable dental composite
FLOW-COLOR, COLOURFLOW - flowable dental composite
FISSURE SEALANT, SEALPRIM - flowable dental composite
COLORANT, COLOURANT - flowable dental composite
SELF SHAPED CHORDS, CHORDS – light cured dental fibres
SHAPED CHORDS – pre-formed fibre dental splints
COMCORD composite and fibre matrix
MASTERBOND, BOND – dental adhesive system
ETCHMASTER, ETCHGEL – dental etching system
SEALING ETCHMASTER
ETCHMASTER TIPS – for dental etching system

ARKON COMPOSITE - kompozytowy światłoutwardzalny materiał stomatologiczny
ciCC, NEXT, ONE, ESC - kompozytowy światłoutwardzalny materiał stomatologiczny
F2 - kompozytowy światłoutwardzalny materiał stomatologiczny
BOSTON, CREATE - kompozytowy światłoutwardzalny materiał stomatologiczny
FIBRE COMPOSITE - kompozytowy światłoutwardzalny materiał stomatologiczny
BOSTON GLAZURA, GLAZE – glazura do kompozytów
FLOW-ART, SILKFLOW – kompozyt typu flow
FLOW-COLOR, COLOURFLOW – kompozyt typu flow
LAK SZCZELINOWY, SEALPRIM – kompozyt typu flow
PODBARWIACZ, COLOURANT – kompozyt typu flow
PODWIĄZKA, CHORDS – światłoutwardzalne włókna stomatologiczne
GĄSIENICA – włókna formowane
Włókno kompozytowe
MASTERBOND, BOND – stomatologiczny system wiążący
WYTRAWIACZ STOMATOLOGICZNY
WYTRAWIACZ DO LAKOWANIA
KOŃCÓWKI DO WYTRAWIACZA

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.