

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 8 February 2018 until 31 October 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 22 September 2019

Issue 10. Certified since 1 November 2010

Certification is based on reports numbered PL/WAW-PL00310

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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**ARKONA Laboratorium
Farmakologii Stomatologicznej
Grzegorz Kalbarczyk**

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 10

Detailed scope

ARKON COMPOSITE – light cured composite dental material
CiCC – light cured composite dental material
F2 – light cured composite dental material
BOSTON – light cured composite dental material
FIBRE COMPOSITE – light cured composite dental material
BOSTON GLAZE – glaze for dental composites
FLOW-ART – flowable dental composite
FLOW-COLOR - flowable dental composite
FISSURE SEALANT - flowable dental composite
COLORANT - flowable dental composite
SELF SHAPED CHORDS – light cured dental fibres
SHAPED CHORDS – pre-formed fibre dental splints
COMCORD composite and fibre matrix
MASTERBOND – dental adhesive system
ETCHMASTER – dental etching system
SEALING ETCHMASTER
ETCHMASTER TIPS – for dental etching system

ARKON COMPOSITE - kompozytowy światłoutwardzalny materiał
stomatologiczny
CiCC - kompozytowy światłoutwardzalny materiał stomatologiczny
F2 - kompozytowy światłoutwardzalny materiał stomatologiczny
BOSTON - kompozytowy światłoutwardzalny materiał stomatologiczny
FIBRE COMPOSITE - kompozytowy światłoutwardzalny materiał
stomatologiczny
BOSTON GLAZURA – glazura do kompozytów
FLOW-ART – kompozyt typu flow
FLOW-COLOR – kompozyt typu flow
LAK SZCZELINOWY – kompozyt typu flow
PODBARWIACZ – kompozyt typu flow
PODWIĄZKA – światłoutwardzalne włókna stomatologiczne
GĄSIENICA – włókna formowane
Włókno kompozytowe
MASTERBOND – 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