DECLARATION OF CONFORMITY

ARKONA Laboratorium Farmakologii Stomatologicznej, Nasutów 99 C, 21-025 Niemce, herewith declares that the product:

According to the European MEDICAL DEVICE DIRECTIVE (93/42/EEC), a Medical Device is:
"(...) material or other article, whether used alone or in combination (...), intended by the manufacturer to be used for human beings for the purpose of (...) investigation, replacement or modification
of the anatomy or of a physiological process (...)and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted by such means(...)."

According to this definition, **SEALPRIM, FISSURE SEALANT (1 g, transparent)**: is a Medical Device.

According to GUIDELINES FOR THE CLASSIFICATION OF MEDICAL DEVICES MEDDEV 2.4/1 Rev. 9, **SEALPRIM, FISSURE SEALANT** is classified as below:

SEALPRIM, FISSURE SEALANT (1 g, transparent): Class IIa, Rule 5.

Duration/For long-term use
Normally intended for continuous use for more than 30 days.

Invasive devices A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
Body orifice Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

Rule 5 - Devices invasive with respect to body orifices; All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa.

SEALPRIM, FISSURE SEALANT (1 g, transparent), is a Medical Device Class IIa and Rule 5 and is in conformity with the Essential Requirements and provisions of the MEDICAL DEVICES DIRECTIVE 93/42/EEC and the standards referenced below have been applied:

- EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009),
- EN ISO 10993-1:2009/AC:2010 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process – Technical Corrigendum 1 (ISO 10993-1:2009/Cor 1:2010),
- EN ISO 10993-3:2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity,
- EN ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity,
- EN ISO 10993-10:2013 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization,
- EN ISO 10993-11:2018 Biological evaluation of medical devices Part 11: Tests for systemic toxicity,

- EN ISO 7405:2008 Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2008),
- EN ISO 7405:2008/A1:2013 Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry – Amendment 1: Positive control material (ISO 7405:2008/Amd 1:2013),
- EN 1641:2009 Dentistry -- Medical devices for dentistry – Materials,
- EN ISO 14971:2012 Medical devices -- Application of risk management to medical devices (ISO 14971:2007),
- EN ISO 6874:2015 Dentistry - Polymer-based pit and fissure sealants
- EN 62366-1:2015 Medical devices -- Part 1: Application of usability engineering to medical devices,
- EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices,
- EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements (ISO 15223-1:2016, corrected version 2017-03),
- European Pharmacopoeia.

ARKONA Laboratorium Farmakologii Stomatologicznej Grzegorz Kalbarczyk, Nasutów 99C, 21-025 Niemce, Poland has established Production Quality Assurance System certified to ISO 13485:2016 (PL10/81903) and Certificate of Conformity with Essential Requirements of European Directive 93/42/EEC (PL19/1102977399) since November 1, 2010 and is under surveillance by SGS Belgium NV, SGS House Noorderlaan 87 2030 Antwerp Belgium (Notified Body 1639).

This conformity assessment is established in accordance with Annex II (excluding Section 4) of MEDICAL DEVICES DIRECTIVE 93/42/EEC; ARKONA Laboratorium Farmakologii Stomatologicznej Grzegorz Kalbarczyk ensures and declares that **SEALPRIM, FISSURE SEALANT (1 g; transparent)** is manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII of MEDICAL DEVICES DIRECTIVE 93/42/EEC and meets its the requirements which apply to it.

Date: 28.02.2020
Signature:

GRZEGORZ KALBARCZYK, Owner