DECLARATION OF CONFORMITY

ARKONA Laboratorium Farmakologii Stomatologicznej, Nasutów 99 C, 21-025 Niemce (SNR Number: PL-MF-000029550), herewith declares that the product:

According to the European MEDICAL DEVICE REGULATION (EU) 2017/745, a Medical Device is:
any (...) material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes (...):

- *prevention, treatment or alleviation of disease,*
- *treatment, alleviation of, or compensation for, an injury or disability,*
- *replacement or modification of the anatomy or of a pathological process or state,*
- *and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.*

According to this definition **SEALPRIM (1 g; colours: transparent)**

Medical device description

SEALPRIM is a translucent light-cured dental composite for sealing dental pits and fissures. SEALPRIM is packaged as a system together with applicator tips. SEALPRIM is a flowable polymer class 2 dental material compliant with the requirements of ISO 6874. SEALPRIM is cured by way of free-radical polymerisation activated by visible light in the blue range (400–500 nm).

Medical device intended purpose

SEALPRIM medical device belongs to the group of pit and fissure sealants intended to protect against caries by sealing all natural pits, fissures and openings on the surface of permanent and deciduous teeth.

List of type, sizes, configurations, variants etc including catalogue numbers covered by the submitted Technical Documentation TF-4:

Basic UDI-DI Code	**590443371TF0047C**		
Medical device	**Size**	**Packaging**	**Colour**
SEALPRIM	1 g	1 syringe and set of applicators	Transparent

According to Annex VIII of European MEDICAL DEVICE REGULATION (EU) 2017/745, above mentioned medical device is classified as below:
SEALPRIM (1 g; colours: transparent) flowable dental composite – **Class IIa, Rule 5.**

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

Invasiveness: **Surgically invasive device**
Surgically invasive device' means:

(a) an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and
(b) a device which produces penetration other than through a body orifice.

RULE 5 – Surgically invasive devices for long-term use
All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as class IIb if they are intended for long-term use, 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 the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class **IIa**.

SEALPRIM (1 g; colours: transparent), is a Medical Device Class IIa and Rule 5 and is in conformity with the General Safety and Performance Requirements and provisions of the MEDICAL DEVICE REGULATION 2017/745/EC and the standards referenced below have been applied:

1. MDCG 2021-24 Guidance on classification of medical devices, October 2021
2. MDCG 2020-6 Guidance on sufficient clinical evidence for legacy devices, April 2020
3. MDCG 2020-5 Guidance on clinical evaluation – Equivalence, April 2020
4. MDCG 2021-1 Rev. 1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional, May 2021
5. EN ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes
6. EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
7. EN ISO 10993-3:2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
8. EN ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.
9. EN ISO 10993-11:2018 Biological evaluation of medical devices Part 11: Tests for systemic toxicity.
10. EN ISO 10993-10:2023 Biological evaluation of medical devices – Part 10: Tests for skin sensitisation
11. EN ISO 10993-18:2020 Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020); EN ISO 10993-18:2020/A1:2023
12. EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
13. EN 1641:2009 Dentistry -- Medical devices for dentistry – Materials
14. EN ISO 14971:2019 Medical devices — Application of risk management to medical devices
15. EN ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer
16. EN ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements,
17. EN ISO 7405:2018 Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry,
18. EN ISO 6874:2015 Dentistry. Polymer-based pit and fissure sealants,
19. EN 62366-1:2015 Medical devices -- Part 1: Application of usability engineering to medical devices.

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 General Safety and Performance Requirements of

European Regulation (EU) 2017/745/EC (No. PL25/00000188) 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 IX section I & III of European Regulation (EU) 2017/745/EC; ARKONA Laboratorium Farmakologii Stomatologicznej Grzegorz Kalbarczyk ensures and declares that **SEALPRIM (1 g; colours: transparent)** is manufactured in conformity with the technical documentation referred to in Annex II of European Regulation (EU) 2017/745/EC and meets its the requirements which apply to it.

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Date: 20.11.2025
Signature:

GRZEGORZ KALBARCZYK, Owner