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, **MASTERBOND (4 ml)** is a Medical Device.

Medical device description

MASTERBOND is one-bottle resin-based dental adhesive system (bonding agent). The device is used to covering teeth tissues before filling placement. Its setting reaction is based on the light-cured polymerization activated by visible light in the blue range (400–500 nm). The device is chemically compatible with all standard light-cured resin-based composite materials.

Medical device intended purpose

MASTERBOND is intended to provide the adhesion between hard teeth tissues and restorations.

List of type, sizes, configurations, variants etc including catalogue numbers covered by the submitted Technical Documentation TF-10:

Basic UDI-DI Code	**590443371TF01077**	
Medical device	**Size**	**Packaging**
MASTERBOND	4 ml	1 pc.

According to Annex VIII of European MEDICAL DEVICE REGULATION (EU) 2017/745, above mentioned medical device is classified as below:

MASTERBOND (4 ml) light-cured dental adhesive system – **Class IIa, Rule 8.**

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 8 - Surgically invasive devices for long-term use
All implantable devices and long-term surgically invasive devices are classified as class IIb unless they are intended to be placed in the teeth, in which case they are classified as **class IIa**.

MASTERBOND (4 ml), is a Medical Device Class IIa and Rule 8 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 10993-10:2013 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization.
10. EN ISO 10993-11:2018 Biological evaluation of medical devices Part 11: Tests for systemic toxicity.
11. EN ISO 10993-18:2020 Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process
12. EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
13. EN ISO 14971:2019 Medical devices — Application of risk management to medical devices
14. EN ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer
15. EN ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements,
16. EN ISO 7405:2018 Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry,
17. EN ISO 4049:2019 Dentistry — Polymer-based restorative materials,
18. PN-EN ISO 29022:2013, Dentistry — Adhesion — Notched-edge shear bond strength test
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 1 & 3 of European Regulation (EU) 2017/745/EC; ARKONA Laboratorium Farmakologii Stomatologicznej Grzegorz Kalbarczyk ensures and declares that **MASTERBOND (4 ml)** 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