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, **COLOURFLOW (1 g, 0,5 g colours: white, yellow, pink, blue, violet, black, red, orange, green)**: is a Medical Device.

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

COLOURFLOW (1 g, 0,5 g colours: white, yellow, pink, blue, violet, black, red, orange, green): Class IIa, Rule 8.

Duration/ Long term
Normally intended for continuous use for more than 30 days

Invasiveness/Surgically invasive device
An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

RULE 8
All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended to be placed in the teeth, in which case they are in Class IIa.

COLOURFLOW (1 g, 0,5 g colours: white, yellow, pink, blue, violet, black, red, orange, green), is a Medical Device Class IIa and Rule 8 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 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 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 ISO 4049:2019 Dentistry – Polymer-based restorative materials,
- 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 **COLOURFLOW (1 g, 0,5 g colours: white, yellow, pink, blue, violet, black, red, orange, green)** 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