DECLARATION OF CONFORMITY

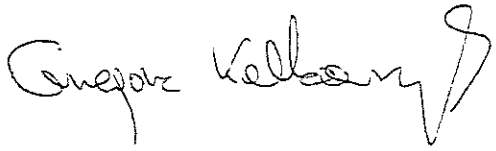
ARKONA Laboratorium Farmakologii Stomatologicznej, Nasutów 99 C, 21-025 Niemce, herewith declares that the product:

PERIOFLUSH – liquid for irrigation of periodontal pockets, is a Medical Device Class I 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 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 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, Nasutów 99 C, 21-025 Niemce has established Production Quality Assurance System certified to ISO 13485:2003, EN ISO 13485:2012 (GB09/77101) since March 30, 2009 and is under surveillance by SGS United Kingdom Ltd, Systems & Services Certification: South West Office, Unit 202B, Worle Parkway, Weston-super-Mare, Somerset BS22 6WA, UK (Notified Body 0120).

Date: 10.07.2018
Signature:



GRZEGORZ KALBARCZYK