EC DECLARATION OF CONFORMITY

According to In Vitro Diagnostic Medical Device Directive 98/97/EC

Name and Address of Manufacturer:

Avantor Performance Materials Poland S.A;
ul. Sowińskiego 11; 44-101 Gliwice

We hereby declare that the below mentioned device conforms to the Essential Principles for Safety and Performance as laid out in the Medical Devices IVD Directive 98/79/EC. Supporting documents are retained by the manufacturer.

In-vitro Medical Device:

Product Name: Hypochlorite NR, Hypochlorite 5%, Hypochlorite 0,5%

Brand Name: J.T Baker

Catalogue Number: 3941, 3936, 3917

Classification: Other, for professional use of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III

This declaration of conformity is valid from 21.05.2021

Prepared by: Regulatory Affairs Officer

DocuSigned by:
Magdalena Onufryjuk
EFC05BED8254408...
May 21, 2021

Signed on behalf of Avantor Performance Materials Poland S.A:

PREZES ZARZĄDU
Jakub Ślusarz

Digitally signed by Ceaicovschi Tudor
Date: 2023.10.20 16:28:29 EEST
Reason: MoldSign Signature
Location: Moldova

Appendix 1

List of applied standards:

EN ISO 14971 :2012, *EN ISO 14971 :2019*	Medical Devices – Risk Management – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
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