EC DECLARATION OF CONFORMITY

This is a declaration issued in accordance with EC Directive 93/42/EEC relating to Medical Devices.

Legal Manufacturer:	*Starpharma Pty Ltd, 4-6 Southampton Crescent, Abbotsford, VIC 3067, Australia*
Manufacturing Site:	*Conforma NV, Zenderstraat 10, 9070 Destelbergen, Belgium*
EC Representative for EU:	*QualRep Services B.V, Utrechtseweg 310 – Building B42, NL 6812 AR Arnhem*

We, Starpharma, herewith declare that the following product conforms to the essential requirements listed in Annex II of the Council Directive 93/42/EEC, excluding section 4:

Device Trade Name:	***Viraleze – Antiviral Nasal Spray***
Item Number:	*N-001*
Classification:	*Class I (according to Annex IX, Rule 5)*
GMDN Code and Term:	*47679 – Nasal moisture barrier dressing*

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential requirements, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

We confirm that the aforementioned product meets the provisions of the following standards:

- *ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- *BS EN ISO 10993-3:2014, Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- *BS EN ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- *BS EN ISO 10993-10:2013, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
- *BS EN ISO 10993-11:2009, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
- *BS EN ISO 10993-12:2012, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*
- *BS EN ISO 10993-18:2020, Biological evaluation of medical devices - Part 18: Chemical characterization of materials*
- *BS EN ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes*
- *BS EN ISO 14971:2019, Medical devices – Application of risk management to medical devices*
- *BS 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*
- *ICH S1A, Need for Carcinogenicity Studies of Pharmaceuticals*
- *ICH S1B, Testing for Carcinogenicity of Pharmaceuticals*
- *ICH S1C, Dose Selection for Carcinogenicity Studies of Pharmaceuticals*
- *ICH S2, Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use*
- *ICH S3A, Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies*
- *ICH S4, Duration of Chronic Toxicity Testing in Animals (Rodent and Non Rodent Toxicity Testing)*
- *ICH S5, Detection of Toxicity to Reproduction for Medicinal Products & Toxicity to Male Fertility*
- *ICH S7A, Safety Pharmacology Studies for Human Pharmaceuticals*
- *ICH Q1A(R2), Stability Testing of New Drug Substances and Products*
- *ICH Q1B, Stability Testing: Photostability Testing of New Drug Substances and Products*
- *ICH Q1C, Stability Testing for New Dosage Forms*
- *ICH Q1E, Evaluation for Stability Data*
- *ICH Q2(R1), Validation of Analytical Procedures: Text and Methodology*

- *ICH Q3B(R2), Impurities in New Drug Products*
- *ICH Q3C(R6), Impurities: Guideline for Residual Solvents*
- *ICH Q6A, Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug products: Chemical Substances*
- *European Pharmacopeia 2.6.12. Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests*
- *European Pharmacopeia 2.6.13. Microbial Examination of Non-Sterile Products: Test for Specified Micro-organisms*
- *United States Pharmacopeia <60> Microbiological Examination of Nonsterile Products - Tests for Burkholderia Cepacia Complex*

The above-mentioned medical device carries the CE mark: CE

Authorised Signatory:

Jeremy Paull
VP, Development and Regulatory Affairs
Starpharma Pty Ltd

22 JAN 2021
Date