

TITRE / TITLE: Declaration Of Conformity Praxiject™

Date effective: 14/02/2023
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Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
Praxiject™ 0.9% Sodium Chloride Prefilled Syringe	3704, 37043, 37053, 37055, 3705C, 3706
Praxiject™ SF 0.9% Sodium Chloride Prefilled Syringe	3705-4

MANUFACTURER		
Name of company	Address	Representative
MedXL, Inc.	285 Labrosse, Pointe Claire (QC)Canada, H9R 1A3	Faiza Benazza Regulatory Affairs Specialist

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax EmergoEurope@ul.com

REGISTRATION INFORMATION	
Notified Body and ID #	CE certificate number
Intertek Semko AB 0413	41316788-03 41316788-03-001

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class IIb Rule 6	Annex II.3 of MDD 93/42/EEC Council Directive	Plastic Syringe: ISO 7886-1, Cap Tightening: ISO 80369-7 Solution: Sodium Chloride Injection, USP Biocompatibility: ISO 10993-1 Chemical Characterization: ISO 10993-18 Sterilization: ISO 11137-2 Packaging: ISO 11607-1 Labelling: EN ISO 15223-1:2021 Risk Management: EN ISO 14971:2019 + A11:2021 Certified Quality System: ISO 13485:2016 MDSAP

MedXL declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices; Directive 93/42/EEC as transposed onto Swedish Law via Instrument LVFS 2003:11 and 2007 Addendum; and Directive 93/42/EEC as transposed onto the national laws of the Member States.

COMPANY REPRESENTATIVE: Faiza Benazza

TITLE: Regulatory Affairs Specialist

SIGNATURE:



DATE: 2023-02-15