MedXL inc. | 285 Labrosse, Pointe-Claire (Qc), Canada, H9R 1A3
T : +1 514.695.7474 | F : +1 514.695.1511 | www.medxl.com

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
CitraFlow™ Sodium Citrate 4% Prefilled Syringe	3854E1, 38543, 38543-1, 38553, 38555

MANUFACTURER		
Name of company	**Address**	**Representative**
MedXL, Inc.	**285 Labrosse, Pointe Claire (QC) Canada, H9R 1A3**	Omar Boulanouar Quality Operation Supervisor

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

REGISTRATION INFORMATION	
Notified Body and ID #	**CE certificate number**
Intertek Semko AB 0413	41316788-02

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class IIa Rule 7	Annex II.3 of MDD 93/42/EEC Council Directive	Plastic Syringe: *ISO 7886-1* *Solution: Anticoagulant Sodium Citrate 4% USP* Cap: *ISO 594-2 or equivalent; ISO 80369-7* Sterilization: *ISO 11737-1, ISO 11737-2, ISO 11137-2* Packaging: *ISO 11607-1* Labelling: *EN ISO 15223-1:2016* Risk Management: *EN ISO 14971:2012* 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 2003:11and 2007 Addendum; and Directive 93/42/EEC as transposed onto the national laws of the Member States.

COMPANY REPRESENTATIVE: Omar Boulanouar

TITLE: Quality Operation Supervisor **SIGNATURE:**

DATE: 24-05-2019

MEDXL INC. CANADA 1991