EXCELSIOR MEDICAL

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
Saline Flush Syringe – 0.9% Sodium Chloride Injection for IV Flush Omniflush® 0.9% Sodium Chloride (NaCl)	NACL2000 CCS500 EM-3513572 EM-3513575 EM-3513576 3240572 3240575 3240576

MANUFACTURER		
Name of company	**Address**	**Representative**
Excelsior Medical, LLC	**1933 Heck Avenue Neptune, NJ 07753 USA**	**Renata DiMarco**

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**
SGS Belgium NV SGS House - Noorderlaan 87 2030 Antwerp Belgium Certification, CE 1639	**US19/819943408**

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class IIa Rule 6	**Annex II (excluding Section 4) of MDD 93/42/EEC Council Directive as amended by 2007/47/EC**	**ISO 13485:2016, EN ISO 13485:2016 (Quality System Certificate Reference Number US06/69306)**

Excelsior Medical declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices as amended by 2007/47/EC and the Directive as transposed in the national laws of the Member States. This declaration is issued under the sole responsibility of Excelsior Medical.

COMPANY REPRESENTATIVE: Renata DiMarco
TITLE: Site Quality Leader/Director of Quality Assurance

SIGNATURE: Renata DiMarco

PLACE OF ISSUE: Neptune, New Jersey

DATE: 31/10/2019
(DD/MM/YYYY)