

# Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
SwabFlush® - 0.9% NaCl Injection, USP	711-600	731-800 751-600
Omniflush® with SwabCap® 0.9% Sodium Chloride (NaCl)	EM-3513576SC	EM-3513575SC EM-3513572SC

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:** 

**PLACE OF ISSUE:** Neptune, New Jersey

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

Effective