

# Declaration of Conformity

<b><u>World Headquarters and Manufacturer</u></b>  ICU Medical, Inc. 951 Calle Amanecer San Clemente, CA 92673 USA		<b><u>Manufacturing Division</u></b> ICU Medical, Inc. 4455 Atherton Drive Salt Lake City, UT 84123 USA	
<b><u>EC REP</u></b> <b><u>Authorized EC Representative</u></b>		Medical Device Safety Service, GmbH (MDSS) Schiffgraben 41 D-30175 Hannover, Germany	
ICU Medical, Inc. declares that the products listed below meet the provisions of the Council Directive 93/42/EEC for medical devices as amended. All supporting documentation is retained under the premises of the manufacturer. Declaration is made for devices manufactured where evidence of successful final inspection and test exists.			
<b><u>Notified Body:</u></b>		National Standards Authority of Ireland (NSAI) Notified Body Number 0050 1 Swift Square, Northwood, Santry, Dublin 9, Ireland	
<b><u>EC Certificate No:</u></b>		252.998	
<b><u>Date of EC Certificate Original Approval:</u></b>		16 June 2016	
<b><u>Signature:</u></b>		 Kriss Anderson Director, Regulatory Affairs, Consumable Medical Devices	
<b><u>Product</u></b>		<b><u>Classification</u></b>	<b><u>Conformity Assessment Route</u></b>
SwabCap		Class IIa	Annex II, Section 3.2

## Product List

PN	Description
EM-SCXT3	SwabCap®
EM-SCXT3-10	SwabPack®, 10 Ct., Bag
EM-SCXT3-25	SwabPack®, 25 Ct., Bag
SCXT3-10-2000G	SwabPack®, 10-Ct., Bag Global
SCXT3-2000G	SwabCap®, 200-ct. Box, Global
SCRC3-10-1600G	SwabPackPlus®, Global
SCXT3-2400G	SwabPack®, 25-ct. Bag Global

End of Product List.