

# 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>Manufacturing Division</u></b> ICU Medical de Mexico, S. de R.L. de C.V. Avenida Cuarzo No. 250 Colonia Rancho Santa Clara, Maneadero Ensenada, Baja California, Mexico 22790	
<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>		252.631	
<b><u>Date of EC Certificate Original Approval:</u></b>		13 Dec 2004	
<b><u>Signature:</u></b>		 Kriss Anderson Director of Regulatory Affairs	
		05 Dec 2018 Date	
<b><u>Product:</u></b>		<b><u>Classification:</u></b>	
Intravenous Line Connector, Needleless (Tego)		Class IIa	
		<b><u>Conformity Assessment Route:</u></b>	
		Annex II, Section 3.2	

## Product List

PN	Description	GMDN Code
011-D1000	Tego® Connector	42750
011-D1005	Tego® Connector	42750
D1000	Tego® Connector	42750

**END OF LIST**

