



# Declaration of Conformity – Class IIa

Form  
7.5-1-7-4

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## MANUFACTURER

Name of company	Address	Representative
Tulip Medical Products	4360 Morena Blvd, Suite 100 San Diego, CA 92117 USA	Marc Pilkington

## 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 – Intertek Semko AB ID# CE 0413	MDSAP ISO 13485:2016 - 0102982 Exp: 6/30/2023 EC - 4130113841

## CONFORMITY ASSESSMENT

Device classification	Route to compliance	Standards applied
Class IIa Rule 6	Annex II, MDD 93/42/EEC Swedish Transposition of Directive – LVFS 2003:11	ISO 13485:2016

Tulip Medical Products declares that the products listed below meet the provision of the Swedish Transposition of Directive 93/42/EEC (LVFS 2003:11). All supporting documentation is retained on the premises of the manufacturer.

This declaration of conformity is issued under the sole responsibility of Tulip Medical Products and applies to all CE marked devices listed above.

**COMPANY REPRESENTATIVE:** Marc Pilkington

**TITLE:** Management Representative

**SIGNATURE:**

**DATE:** 5/24/2021

## PRODUCT IDENTIFICATION



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Product name	Model/number	
Tulip Gems™ Single-Use, Disposable Cannulas & Accessories	<b>Cannulas</b> DC1SLTON1320 DC1SLCAR1410 DC1SLCAR1415 DC1SLCAR1315 DC1SLSOR1320 DC1SLMIL1415 DC1SLSPO1415 DC1SLINF1412 DC1SLINF1415 DC1SLINF1420 DC1SLINJ2004 DC1SLINJ1905 DC1SLINJ1807 DC1SLINJ1709 DC1SLINJ2306 DC1SLINJ2505	
Product name	Model/number	Model/number
Tulip Gems™ Single-Use, Disposable Cannulas & Accessories	<b>Accessories/Transfers</b> DATLLLL1.2mm DATLLLL1.4mm DATLLLL2.4mm DNFT90G2 DNTS DNTC <b>Accessories/Lock</b> DJS220 DJS360G2 DMS160G2 <b>Accessories/Syringes</b> SYR1LLBX SYR10BDBX SYR20BDBX SYR60BDBX	<b>Kits</b> DArthrex Kit - ABS10055 DPK-GOLD-TNF DPK-SFB-TNF DPK-SFB DPK-SFF-TNF DPK-SFF DPK-CAR DPK-CAR-TNF DPK-MIL DPK-MIL-TNF DPK-TON DPK-TON-TNF DPK-SOR DPK-SOR-TNF DMICRO