EC Declaration of Conformity

DTR Medical Ltd declares that the Device listed below are in conformance with PPE Regulation 2016/425.

These products are classed as Category III Personal Protective Equipment (PPE) by the European PPE Regulation (EU) 2016/425 and have been shown to comply with this Regulation through limited testing against the Harmonised European Standard EN 166:2001

This Declaration of Conformity is issued under the sole responsibility of the manufacturer

Group	Product Family	Product Code	Description	Classification	GTIN (piece/ carton)
1	Face Visor	CM-5001R	Reusable Innovia Face Visor	Category III	Base 05060411987166 Box 05060411987173

Classification: Category III PPE under PPER 2016/425 Annex II - Module B and C2 (certificate no.2777/15339-01/E00-00)

Notified Body: SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland.
Notified Body No. 2777

Manufacturer: DTR Medical Ltd 17 Clarion Court, Clarion Close, Enterprise Park, Llansamlet, Swansea SA6 8RF, UK

Issue: 02

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Place of issue: 17 Clarion Court, Enterprise Park, Swansea, SA6 8RF, UK
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