

**TECHNICAL FILE****Product:** Aspirating Needles, Aspirating Cannula  
& Flushing Needles**Index Item:** 15  
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**Issue:** 02**EC Declaration of Conformity**

DTR Medical Ltd declares that the medical devices listed below are in conformance with Directive 93/42/EEC (and subsequent amendments) Annex V and Annex I (Essential Requirements) and with the UK Statutory Instrument SI-618 transposing such Directive.

**Device:**

- ASN2018** Aspirating Needle 18G x 335mm & luer, double packed. Packed in 20's
- ASN5018** Aspirating Needle 18G x 335mm & luer, double packed. Packed in 50's
- ASN2518** Aspirating Needle 18G, 5mm x 335mm & luer, double packed. Packed in 20's
- TAC20LC** Tibbs Arterial Cannula Large Cone, std length, double packed
- TAC20SC** Tibbs Arterial Cannula Small Cone, std length, double packed
- TAC20LO** Tibbs Arterial Cannula Large Olive, std length, double packed
- TAC20SO** Tibbs Arterial Cannula Small Olive, std length, double packed
- TAC20MO** Tibbs Arterial Cannula Micro Olive, 2.5mm OD, std length, double packed
- TAC20XLC** Tibbs Arterial Cannula X Large Cone 8mm OD, extra-long, double packed
- TAC20XXLC** Tibbs Arterial Cannula XX Large Cone 12.25mm OD, extra-long, double packed
- TAC2003** Tibbs Arterial Cannula, Set of 3 sizes, double packed
- HFN2001** Heparin Flushing Needle, double packed
- HFN2081** Heparin Flushing Needle 85mm, double packed

**Classification:** Class IIa (under Rule 6)**Issue:** 02**Signed:** A Davidson



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**Notified Body:** BSI Group Neverlands BV  
Notified Body No. 2797  
Certificate Number: MD 696155

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

**Andrew Davidson**  
**Managing Director**

**Date:** 21/3/19

**Issue:** 02

**Signed:** A Davidson

