Tournistrip
Declaration of Conformity

Product Identification			
Product Name	Product Part Number	Description	Date CE Marked
Tournistrip	95.1006 (5490LHT236/SARSTEDT200)	Tournistrip single use tourniquet 200 Pack	30th Dec 2018
Tournistretch	95.1008 (43451TPEO/SAR25)	Tournistretch single use tourniquet 25 pack	30th Dec 2018

Manufacturer			
Name of Company	Brand Name	Address	Representative
ASep Healthcare Ltd	Tournistrip Tournistretch	18 Tapton Way, Wavertree Business Village, Liverpool, L13 1DA	Mirela Adamovici Head of Quality

Registration Information	
Notified Body & ID #	CE Certificate Number
BSI 0086	N/A
Contracted EU Representative	Obelis SA, Bd Général Wahis, 53 B-1030 Brussels Belgium

Conformity Assessment	
Device Classification	Route to Compliance
Class I, Rule 1	Annex IX, MDR (EU) 2017/745
Standards Applied (Details available in MDTF002, Section 6*)	BS EN ISO 13485:2016, Quality Management Systems BS EN ISO 14971:2012, Application of Engineering and Risk Management BS EN 62366:2015, Application of Usability Engineering BS EN 1041:2008+A1:2013, Information supplied by the manufacturer BS EN ISO 15223-1:2012, Symbols to be used with Medical Devices

* Note: Standards referenced are valid at the date of issue of this conformity declaration

Declaration

ASep Healthcare Ltd declares that the Tournistrip device is in conformity with the Essential Requirements and provisions of the European Regulation MDR (EU) 2017/745 of the European Parliament and of the Council of the European Communities.

Title: Chief Executive Officer Date: 3rd March 2021

Signature:

ASEP HEALTHCARE LIMITED
Unit 18, Tapton Way, Wavertree Business Village Liverpool L13 1DA
EN-ISO 13485:2016 Certificate: MD667988
COMPANY NUMBER: 6491984