



## **DECLARATION OF CONFORMITY**

<b>Manufacturer:</b> Roma Medical Aids Ltd. York Road Bridgend Industrial Estate Bridgend CF31 3TB	<b>Authorised EU Representative:</b> Roma Medical Aids Ltd. Westplain 12-14 Rotterdam The Netherlands
<b>Company Registration No. 1869285</b>	
<b>SRN: TBC</b>	

This declaration of conformity is issued under the sole responsibility of Roma Medical Aids Ltd.

**Product(s) Code & Name: 2203**

Including all colour and model variants:

2203/D, 2203A & 2203J

**Other Trade Names: N/A**

**UDI-DI: TBC**

**Classification: Class 1 Medical Device**

**First Marketed: 2003**

**Main Standards Applied: CE, EN ISO 9001, EN ISO 13485, EN ISO 14971, EN 12182, EN 1985, EN ISO 11199-1**

Roma Medical Aids Ltd declares that the above-mentioned product(s) conform to the requirements of the Medical Devices Regulation (EU) 2017/745.



R Pitt BSc (Hons)  
Technical Manager

Date of Issue: 07/03/20

Place of Issue: Bridgend

On behalf of Roma Medical Aids Ltd.