

Declaration of conformity

The manufacturer: **Score B.V.**
Feithspark 5
8356 BX Tolbert
The Netherlands
SRN **NL-MF-000006060**



declares under exclusive responsibility that the product

Product name: **Vena[®] Armrest**
Phlebotomy armrest – Bloedafname armlegger

Basic UDI-DI: 871722818VENA-ARMR-01UR

Description: The Vena[®] Armrest is a medical device intended to support the arm of the patient during phlebotomy, blood drawing, blood donation, plasma donation, or injection.
The Vena Armrest is available in fixed and multi-adjustable types.

Article number(s): 908x.xxxxx. (x.xxxxx referring to type)

has been designed, produced and tested according to the following harmonized standards for medical devices

ISO 9001:2015 Quality management systems
ISO 14791:2019 Medical devices - Application of risk management to medical devices

and is in compliance with all essential requirements of **Medical Device Regulation (MDR) EU 2017/745**

In accordance to the classification rules set out in this regulation the product is: **Class I**

Date: September 19, 2023
Place of issue: Tolbert, The Netherlands
Name: Mr. Mark Nauta
Title: Managing Director
Signature:

