EU Declaration of Conformity

Manufacturer:
Unimed Medical Supplies, Inc
SRN: CN-MF-000001480
Address:
Bld#8, Nangang 3rd Industrial Park, Tangtou,
Shiyan, 518108, Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
Obelis s.a.
SRN: BE-AR-000000106
Address:
Boulevard Général Wahis 53
1030 Brussels, BELGIUM

Device Name:	Reusable NIBP Cuff
Trade Name:	Refer to attachment *List of Devices*
Device Model:	Refer to attachment *List of Devices*
GMDN Code:	34978
CND Code:	Z1203020599
Basic UDI-DI:	69456648RNC1ZU
Classification:	I (According to Rule 1 of Annex VIII of Regulation (EU) 2017/745)

We hereby declare under our sole responsibility that the above mentioned device(s) comply(ies) with the provisions of the Regulation (EU) 2017/745 on Medical Device.

Conformity Assessment Procedure:	Annex II and III of Regulation(EU)2017/745
Standards and CS Applied:	Refer to attachment *List of Applied Standards and CS*

We hereby also declare under our sole that the product(s) listed in Annex comply(ies) with the provisions of Directive 2011/65/EU.

The CE Mark:

CE

Shenzhen, September 3, 2021
Place, Date of Issue

General Manager, FrankZhang
Position, Name, Signature

Attachment of EU Declaration of Conformity: List of Devices

List of Devices

Device Model	Device Trade Name and General Description
U1869S	Reusable with bladder NIBP Cuff/single tube/large adult (33-47cm)
U1880S	Reusable with bladder NIBP Cuff/single tube/adult (25-35cm)
U1881S	Reusable with bladder NIBP Cuff/single tube/pediatric (18-26cm)
U1882S	Reusable with bladder NIBP Cuff/single tube/infant (10-19cm)
U1883S	Reusable with bladder NIBP Cuff/single tube/neonate (6-11cm)
U1884S	Reusable with bladder NIBP Cuff/single tube/adult thigh (46-66cm)
U1885S	Reusable with bladder NIBP Cuff/single tube/small adult (20-28cm)

Attachment of EU Declaration of Conformity: List of Applied Standards and CS

List of Applied Standards and CS

EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2013	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Sensitization
EN ISO 14971:2019	Medical devices-Application of risk management to medical devices
EN ISO 81060-1:2012	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type