CE-DOC-FHT-20201130 (1.0)

EC Declaration of Conformity

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

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

Device Name：	Fetal transducer cases(Fetal Heart)
Model：	UFU200-10,UFU200-20,UFU300-10,UFU300-20,UFU700-20,MS3-109301, UFU700-30,
GMDN Code：	41917
Classification：	I I b (According to Annex IX of directive 93/42/EEC)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: Annex II excluding(4) of Directive 93/42/EEC
Standards Applied Refer to attachment *Applied Standards List*
Notified Body:

TÜV SÜD Product Service GmbH
Ridlerstraße65, 80339, München, Germany
Certificate No.: G1 066456 0022 Rev.00
Issue date: 2019-09-24
Expiry date: 2023-06-08

The CE Mark：

CE 0123

Shenzhen, 2020-11-30
Place, Date of Issue

General manager, Frank Zhang
Legally binding signature, Function

Applied Standards List

Device Name:	Fetal transducer(Fetal Heart)
Applied Standards:	
EN ISO 15223-1:2016	Medical device – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
ISO 10993-1:2009	Biological evaluation of medical devices-Part 1:Evaluation and testing
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Sensitization
ISO 14971:2012	Medical devices-Application of risk management to medical devices
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 62366-1:2015	Medical devices - Part 1 Application of usability engineering to medical devices
IEC 60601-2-37：2007	Medical electrical equipment-Part 2-37:Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment