DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING IN VITRO DIAGNOSTIC MEDICAL DEVICES

Manufacturer:	**BioCare Corporation** **4F, No.12, Ln. 5, Sec. 2, Nanshan Rd. Luzhu Dist. 33852 Taoyuan City,TAIWAN**
European Representative:	**MedNet GmbH** **Borkstrasse 10, 48163 Muenster, Germany**
Product Name:	**Non-Invasive Blood Pressure Monitors**
Trademark / Model:	**vTrust 701DH**

GMDN(UMDNS) Code: **30892**

Classification (MDD, Annex IX): **Class IIb according to Directive 93/42/EEC, annex IX, rule 10**

Conformity Assessment Route: **Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. Manufacture is exclusively responsible for DoC.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC).

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany
Identification number:	CE0123
ISO 13485 Certificate(s):	**G1 16 11 77360 014**
Expire date of the Certificate:	2022-01-22
Place, Date of Issue:	Taiwan, March 12, 2019
Signature:	
Name:	Terry Liu
Position:	Management Representative

CE 0123

Document No. T0902-D00301