Making life better
呵护美好生活

Declaration of Conformity

Manufacturer: **Better Life Medical Technology Co., Ltd**
Room 201, Bldg.6, No.188 Fuchunjiang Rd, Suzhou High-tech District, Suzhou, 215153, Jiangsu Province, China

European Representative: **Wellkang Ltd**
Enterprise Hub， NW Business Complex，
1 Beraghmore Road, Derry， BT48 8SE， Northern Ireland, UK.

Product Name:	**Patient Monitor**
Model Number:	**Vitavue10、Vitavue12、Vitavue15、IRIS200、IRIS300、IRIS400、IRIS500 NESO100、NESO200、NESO300**
UMDNS/GMDN Code:	**33586**
Classification (MDD, Annex IX):	**IIb, rule 10**
Conformity Assessment Route:	**Annex II.3**

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. We are exclusively responsible for the Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC

Notified Body:	**TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany**
Identification number:	**CE0123**
(EC) Certificate(s):	**No. G1 003960 0002 Rev.02**
Expire date of the Certificate:	**2023-10-28**
Start of CE Marking:	**2019-11-7**
Place, Date of Issue:	**Suzhou, 2021/05/17**

Signature:

Name: James Lu

Position: Management Representative