CE 2460

DECLARATION OF CONFORMITY

We, Uzinmedicare Co., Ltd.

54, 56, Dongtansandan 5-gil, Hwaseong-si, Gyeonggi-do, 18487, Republic of Korea

declare under our sole responsibility that the product ;

Product	:	**Electric Breast Pump**
Classification	:	**Class IIa (by rule 11 of annex IX)**
Model/ Type	:	**Spectra S1Plus** **(Alias: Spectra S1+, Spectra S1, Clinicare S1Plus, Spectra S1professional)** **Spectra S2Plus** **(Alias: Spectra S2+, Spectra S2, Clinicare S2Plus)**
Serial No.	:	

is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC, As amended by 2007/47/EC is in conformity with the harmonized standards

EN ISO 13485:2016, EN ISO 14971:2012, EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN ISO 15223-1:2016, EN 1041:2008, ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-10:2010, EN 62366:2008, EN 60601-1-11:2010, EN 62304:2006/AC:2008, EN 60601-1-6:2010, EN 14350-2:2004, 21 CFR 177.2600, 21 CFR 177.1520

Is subject to the procedure set out in AnnexⅡ (excl. Section 4) of Directive 93/42/EEC under the supervision of Notified Body number 2460 , DNV GL Presafe AS: Veritasveien 3 1363 Høvik Norway. The Manufacturer is exclusively responsible for the declaration of conformity.

Manufacturer .

Uzinmedicare Co., Ltd.

Gyeonggi-do, Republic of Korea, Jan 22, 2021
(Place) (Date)

Byung-Wook Min, President
(Name) (Position)

(Signature)

Eu representative

OBELIS S.A

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