PLASTIFLEX Healthcare	Document Title : EC DECLARATION
	Document number : FRM423-05-06 Record number : STED 2.3 – update 08/06/2023

EC DECLARATION OF CONFORMITY

We,

Plastiflex Group NV
Buntjesstraat 13
B-3583 Paal-Beringen
Belgium

hereby declare under our sole responsibility that the CE marked product(s) as specified in the appendix to which this declaration relates,

have been classified as Class IIa and are in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC (14 June 1993) concerning medical devices as amended by Directive 2007/47/EC

and are in conformity with the relevant harmonized standards as documented in TF document ”List of Applicable Standards”

and are subject to the procedure set out in Annex II of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC

and are in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88.)

This declaration is made on base of :

- the quality assurance certificate : N°. BE19/819943668
- and the CE Annex II excl.§ 4 certificate : BE19/819943667

delivered by Notified Body n° 01639, SGS Belgium NV on : 17/09/2019

This certificate is valid for devices released from the following site (s) :

Plastiflex Group NV
Buntjesstraat 13
B-3583 Paal-Beringen
Belgium

Date :

Name : Patricia Dubois
Function : QA/RA

Patricia Dubois (Signature)
Digitally signed by Patricia Dubois (Signature)
Date: 2023.06.27 15:01:22 +02'00'

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Product Group	Product name commercial	JPN CODE
Classic	Classic 15	HUE15018GT0WWGGI
Classic	Classic 19 CPAP Tubing	HUE19018GT0SSGGK
Classic	Classic FL 15	HWN15018GT0WWGGI
Classic	Classic FL 19	HWN19018GT0WWGGI