



Building 14, No.2058, Haizang West Rd, Luzhi Town,
Wuzhong District, Suzhou City, Jiangsu Province 215127, China
江苏省苏州市吴中区角直镇海藏西路2058号14幢
Tele: 0512- 5799 9886

DECLARATION OF CONFORMITY

Manufacturer: Viecura Medical Group Limited

Address: Building 14, No.2058, Haizang West Rd, Luzhi Town, Wuzhong District, Suzhou City, Jiangsu Province 215127, China // 99 Bami Road, Nangang Industrial Park, Zhangpu Town, Kunshan City, Jiangsu Province 215326, China

EC representative: OBELIS S.A

Product Code	Product description
6010.2	Hip Protector Small
6010.3	Hip Protector Medium
6010.4	Hip Protector Large
6010.5	Hip Protector Extra Large (XL)
6010.6	Hip Protector Extra Extra Large (2XL)

Address of EC representative: Bd. General Wahis, 53 1030 Brussels, Belgium

Product Classification: **None sterilized, Medical Device Class I**

We hereby state that:

Those above products with CE marking which are manufactured by our company all comply with EU Medical Device Directives MDR(EU)2017/745 and realize their expected uses.

All CE files have been certified by the company and relevant notifying body, consequently their authenticity has been guaranteed.

Directive we are following:

European Union Committee Medical Device Directives MDR(EU)2017/745

Standards we are implementing:

**MDR(EU)2017/745; EN 1041:2008; EN ISO15223:2012; EN ISO 14971:2020.
EN ISO 10993-1:2010; EN ISO 10993-5:2009; EN ISO 10993-10 :2010; FZft73024:2006**

Viecura Medical Group Limited hereby confirm that the above listed products, including all raw materials, processing aids and packaging used during the manufacture and packing of the product do not contain the following:

Substances which are carcinogenic, mutagenic, or toxic to reproduction of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 in a concentration above 0.1% weight by weight (W/W):



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H300	H301	H310	H311
H330	H331	H304	H370

Does not contain any substances on now valid candidate list art:59 in EC 1907/2006 REACH above 0,1% Weight by weight (W/W)

Does not contain any of below substances with intention of giving a microbial function:

- Chlorhexidine or its compounds, example 55-56-1
- PHMB: 28757-47-3, 32289-58-0 and 28757-48-4
- PHMG: 57028-96-3
- Silver or its compounds
- Copper or its compounds
- Triclosan 3380-34-5
- Trichloroethane 101-20-2
- Quaternary ammonium compounds

SIGNED:

DIARMUID GALLAGHER

EU Sales Manager

12/01/2022