

EU DECLARATION OF CONFORMITY

We (Manufacturer) declare on our responsibility that the below mentioned medical devices are in conformity with the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Business name: Glomarket bv

Address: Registered office
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Office & Warehouse:
Zwaarveld 34
9220 Hamme
Belgium

SRN manufacturer: BE-MF-000000730 (**Eudamed**)

Authorised representative:

- Mr. Frederik Baeckelmans
- Mr. Nico De Wilde

Basic UDI-DI: Not yet active / Operational by the EU

Device name: Cap with sewn-in protectors

Trade name: **Ribcap**

ribcap 



Intended purpose:

Non-exhaustive list:

- Neurological conditions
- Reduced mobility
- Prevention
- Fall & injury
- Epilepsy
- Autism
- Special needs
- Oncology

Non-invasive medical device

Risk class, Class I, according to the Annex VIII. , rule 1 of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Conformity Assessment procedure: Annex II. + III. of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Model:

Jackson / Lenny / Iggy / Chessy / Fox / Palmer / Hardy / Björk / Harris / Dylan / Bieber / Freddie / Baseball cap / Baseball cap Kids / Billie



The present declaration of conformity is issued on the responsibility of the manufacturer.

Place and date of issue of the declaration: Belgium – 9220 Hamme 01 January 2021

Name and function: Mr. Frederik Baeckelmans – Manager

A handwritten signature in black ink, appearing to read 'F. Baeckelmans', written over a white background.