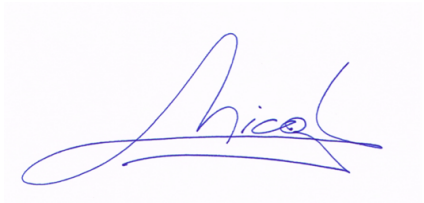
ribcap	EU 2017/745 MEDICAL DEVICE REGULATION DECLARATION OF CONFORMITY	**Document No**	TF-01-Ann2
		Rev Date-No	00 / NA
		Publish Date	01.03.2022
		Page	**1** of **3**

Manufacturer Name(*)	GLOMARKET BV
Manufacturer Adress (*)	Quastraat 6 A 9270 Laarne Belgium
Single Registration Number (SRN No)	BE-MF-000000730
Product Name (*)	RIBCAP
Catalog/Model No (*)	TF-01-Ann6 Model List
Intended Purpose (*)	RIBCAP® head protector models serve to protect from head injuries caused by uncontrolled falls or sequences of movements. They cover fall hazards with the minor or medium potential for injury through the protective effect of the shock-absorbing foam padding. The top of the head is almost completely enclosed by pads. The head protector comes in different sizes ranging from 47cm to 65cm. (18.5” to 25.6”).
Basic UDI-DI (*)	542503898RIBCAPEL
Product Classification / Classification Rule (*)	**RIBCAP** is Class I according to Rule 1 under Annex VIII of EU 2017/745 regulation
Conformity assessment route	EC self-conformity assessment for Class 1 devices following the Regulation.
Conformity Assessment Procedure (*) (Additions executed in the product evaluation are marked)	Annex II and Annex III of 2017/745 MDR

Place:

Date of Issue



DE WILDE NICO
CO-OWNER

01/04/2022

Name Surname
Title – Date- Signature

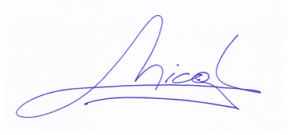
Name Surname
Title – Date- Signature

Declaration of Conformity – Annex II: Applied Standard List

No	Standard /Document No	Standard / Document Name	Type	Harmonized	Revision Date
1	2017/745/EC	Medical Device Regulation	Regulation	NA	2017
2	MDCG 2019-4	Timelines for registration of device data elements in EUDAMED	Guidance	NA	2019
3	MDCG 2019-15	Guidance Notes for Manufacturers of Class I Medical Devices	Guidance	NA	2015
4	MDCG 2020-2 rev. 1	Class I Transitional provisions under Article 120 (3 and 4) – (MDR)	Guidance	NA	2020
5	MDCG 2020-7	Guidance on PMCF plan template	Guidance	NA	2020
6	MDCG 2020-8	Guidance on PMCF evaluation report template	Guidance	NA	2020
7	MDCG 2020-5	Guidance on clinical evaluation – Equivalence	Guidance	NA	2020
8	MDCG 2020-13	Clinical evaluation assessment report template	Guidance	NA	2020
9	MDCG 2021-24	Guidance on classification of medical devices	Guidance	NA	2021
10	EN ISO 14971	Medical devices — Application of risk management to medical devices	Standard	H	2019+A11:2021
11	EN ISO 13485	Medical Devices- Quality Management Systems - Requirements for Regulatory Purposes	Standard	H	2016+A11:2021
12	EN ISO 20417	Medical Devices - Information to be supplied by the manufacturer	Standard	NA	2021
13	EN ISO 15223-1	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirement	Standard	H	2021
14	EN 62366-1	Medical devices -- Part 1: Application of usability engineering to medical devices	Standard	NA	2015/A1:2020

Place:

Date of Issue



DE WILDE NICO
CO-OWNER

01/04/2022

Name Surname
Title – Date- Signature

Name Surname
Title – Date- Signature