

EC DECLARATION OF CONFORMITY

We,

Reskin Medical nv
Industrieweg 114
3980 Tessenderlo-Belgium

SRN: BE-MF 000012226

hereby declare under our sole responsibility that the CE marked products to which this declaration relates.

Non-sterile Single use patch with self-adhering silicone surface

With the intended use:

- ❖ Protective patch to be applied on the skin to avoid skin lesions caused by friction and shearing forces

(with product variants mentioned in annex)

Have been classified as a Class I, according to Annex VIII, rule 4, of the Medical Device Regulation MDR 2017/745.

And is in conformity with the General Safety and Performance requirements Annex I and provisions of the Medical Device Regulation 2017/745

And is in conformity with the harmonized standards

- ❖ EN ISO10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

This declaration is made on base of the FAGG registration , n° BE/CA01/1-06700-10003-CLI delivered by FAGG, Federal Agency of Drugs & Health Care Products on 02.12.2021

Signature : _____

date :07.08.2023

Name : Stany Haentjens
Function : General Manager Reskin Medical nv



Annexe 1:

This product is on the market with following names and sizes:

Reskin Sport; BASIC UDI: 5430002895SDSCVE				
Portfolio		units/pouch		UDI code
Reskin Bike Patch		5		05430002895772
Reskin Lady Bike		5		05430002895819
Runners Combi		2 nipple, 2 blister, 1 square patch		NA
Variable XXL 35		1		NA

