

Title	Product	Doc.ID	Rev
Declaration of conformity - MDD	P01	P01-1.1.1	2

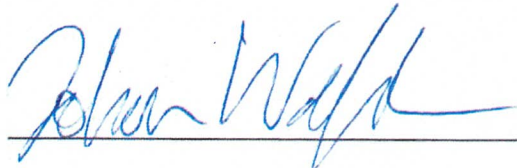
Declaration of conformity - MDD

Product:	PU sensor (P01)
Product version:	Ver 1
Manufacturer:	PU sensor AB Snickaregatan 40 582 26 Linköping Sweden
Classification:	Class I
Conformity assessment route:	Annex VII
Notified body:	Not applicable
EC Certificate:	Not applicable

This declaration of conformity is issued under the sole responsibility of the manufacturer.

We hereby declare that the above-mentioned device(s) comply with the Swedish medical device regulation LVFS 2003:11 transposing European Medical Devices Directive 93/42/EEC.

Signed for and on behalf of PU sensor AB:



Johannes Walfridsson, CEO

2022-03-31

Date

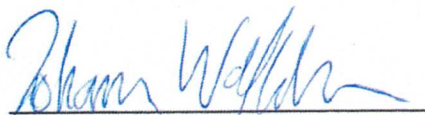
Title	ID	Rev
EU Declaration of conformity	PO2-1.1.1	1

EU Declaration of conformity

Manufacturer			
Registered place of business:		PU sensor AB Snickaregatan 40 582 26 Linköping Sweden	
SRN:		SE-MF-000037368TBD	
Device information			
Product name:	PU sensor		
Included articles:	Article no	Article name	UDI-DI
	PU002	Kit	(1)73501554802011
	MU002	Main unit	(1)73501554802028
	QI001	Charger	(1)73501554802042
	SP001	Sensor plate	(1)73501554802059
	IF001	Inflatable cushion	(1)73501554802066
Basic UDI-DI:		73501554802NU	
Intended purpose:		The intended use of the product is identifying patients with risk of developing pressure ulcers. The product is meant to be an objective and more precise complement to the scales that are used for pressure ulcer risk assessment today.	
Medical Device Regulation specifics			
Risk class:		Class I	
Reference to any CS used and in relation to which conformity is declared:		No CS used	
Name and identification number of the notified body:		N/A	
Conformity assessment procedure performed:		2017/745 annex I, II	
Identification of the certificate or certificates issued:		N/A	
Additional information:		-	

This declaration of conformity is issued under the sole responsibility of the manufacturer.
The device that is covered by the present declaration is in conformity with Regulation (EU) 2017/745.
This declaration of conformity is signed by electronic signature including date of issue of the declaration. Place of signature shall be interpreted as electronic signature.

Signed for and on behalf of PU sensor AB:



Johannes Walfridsson, CEO

2024-02-29

Date