

EU Declaration of Conformity (DoC)

We

Company Name:	1922 PTY Ltd
Postal Address:	Potts Point 2011
Postcode:	NA
City:	New South Wales, Australia
Telephone:	+61 437 773 230
E-mail address:	pete@notjustapatch.com

Declare that the DoC is issued under our sole responsibility and belongs to the following product:

Apparatus / Model:	Not Just A Patch - adhesives for Continuous Glucose Monitors
Type:	Bandage / Tape, used as a medical treatment aid with the use of adhesive
Batch:	33521 (Associated GMDN ID)
Classification of Product:	Classification according to EU 2017 / 745 (Medical Devices) Annex VIII Rule I is Class I.

Object of the declaration:





The object of the declaration above is in conformity with the relevant Union Harmonization legislation:

EU 2017/745, Annex I (<i>General Safety and Performance Requirements</i>)	EU 2017/745, Article 2
EU 2017/745, Annex IX	

The following harmonized standards and technical specifications have been applied:

EN ISO 14971:2012	EN ISO 10993-1:2009
EN ISO 15223-1:2016	EN ISO 1041:2008 / A1:2013
IEC 62321:2008	MEDDEV.2.7.1 Rev.4


Notified Body:

Name of Notified Body:	European Commission, 200 Rue de la Loi, Brussels B-1049, Belgium
Registration ID of Notification Body:	745.90.292013
Certification Registration ID:	(tbc)

Additional Information:

N/A

Signed for and on behalf of:

Place of Issue:	Prague, Czech Republic
Date of Issue:	22 nd August 2022
Full Name:	Mgr. Stephen Brian Purdie
Position:	Judicial Magistrate, Prague Advocate Offices
Signature:	

Manufacturer:	Potts Point 2011, New South Wales, Australia
Date of Issue:	17 th August 2022
Full Name:	Peter Lomas
Position:	Chief Executive Officer, 1922 PTY Ltd.
Signature:	<i>Pete Lomas</i>