

## EU Declaration of Conformity

Document number: 2022 / 9D1-6633841-EN-00  
Manufacturer or representative: SPA Global s.r.o.  
Address: Washingtonova 1624/5, 110 00, Prague, Czech Republic  
Brand name or trade mark: Not Just a Patch  
Product type: Not Just a Patch – Adhesive Patch for Continuous Glucose Monitor  
Product designation: OT 12\_24V 33521

The designated product(s) is (are) in conformity with the relevant Union harmonisation legislation:

EU MDR Class I Device – EU 90/385/EEC Active Implantable Medical Devices Directive Regulation (EU) 2017/745 of the European Parliament and the council of 5<sup>th</sup> 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 (Text with EEA relevance) Text with EEA relevance.


The following harmonized standards and technical specifications have been applied:

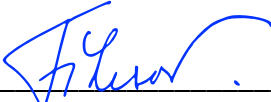
EN ISO 14971:2012 – Risk Assessment of medical Devices  
EN ISO 15223-1:2016 – Identification of Symbols for Medical Labelling  
EN ISO 10993-1:2009 – Systematic and Assessment of Degradation of Medical Devices  
EN ISO 1041:2008 / A1:2013 – Additional Information provided by manufactured materials used in Trademark or Medical Devices  
MEDEV 2.7.1 Rev.4 – EU Medical Device directives and operational principles


The last two digits assigned to the CE marking was affixed: 22.

Place and date of signatures: Prague, Czech Republic 22<sup>nd</sup> August 2022

Signatures:

  
\_\_\_\_\_  
European Legal Representative,  
Legal Counsel and Compliance  
Officer  
**Mgr. Stephen Purdie**

  
\_\_\_\_\_  
Chief Executive Officer,  
1922 PTY Ltd.  
**Pete Lomas**



Customer service contact: SPA Global s.r.o., Washingtonova 1426/5, Prague 1, 110 00, Czech Republic

This declaration of conformity is issued under the sole responsibility of the manufacturer or representative. It certifies compliance with the indicated Directives, but implies no warranty of properties.