

## Declaration of Conformity

for CPAP Pillow

**European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states**

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

<b>General Product Name:</b>	CPAP Pillow
<b>Legal Manufacturer: (Name on Label)</b>	<b><u>Choice One Medical</u></b> 1 Westside dr., unit 2A, Toronto, ON M9C 1B3 Canada
<b>Variants:</b>	As per Appendix II (This document) – Product Listing/Schedule
<b>Intended Use:</b>	Specifically designed to encourage easier breathing by alleviating pressure from CPAP masks to continuously give a deep relaxing sleep.
<b>MD Directive Classification:</b>	Class I
<b>Notified Body:</b>	Not Applicable for Class I
<b>EU Authorised Representative:</b>	Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.
<b>Medical Device Directive Assessment Route:</b>	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

**Name** Kari Neil **Position** Director, Marketing and Sales

**Signed**  **Date** 08/10/2020

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

**Appendix I – Applicable Standards**

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
MEDDEV 2.12-1 rev 8, December 2013	Guidelines on a Medical Device Vigilance System.
MEDDEV 2.7/1: rev. 4, June 2016	Clinical evaluation: A guide for manufacturers and notified bodies.

**Appendix II – Product Listing/Schedule**

Part/Catalogue Number	Description/Name	GMDN Code
627843461241	BEST IN REST™ Memory Foam CPAP Pillow	35503
645759689764	BEST IN REST™ Memory Foam CPAP Pillow with Cooling Gel	35503
669002831403	BEST IN REST™ Pillowcase for Memory Foam CPAP Pillows	47453

**Version History**

Version	Compiled by	Date	Description
1.0	Kari Neil	08/10/2020	First issue