Itamar Medical Ltd.

Doc: RDF069110	Edition: 1	Edition Date: 1 May 2020	Page: 1 of 2

EC Declaration of Conformity – WatchPAT™ONE

We, Itamar Medical LTD , located in CAESAREA, Israel , manufactures of PAT – Peripheral Arterial Tonometer a non invasive device for the detection of peripherial arterial tone changes as a diagnostic aid for Sleep disorders, Myocardial ischemia, endothelium dysfuctions, as detailed hereunder, that are placed in the European market, declare that our products conform and meet the requirements of the Medical Device Directive 93/42 EEC, as amended by 2007/47/EC, including the essential requirements set out in Annex I.

Appointed Notified Body: BSI (NB # 2797) for the requirements of MDD 93/42/EEC Annex II, as amended by 2007/47/EC.

Address of manufacturer
PO Box 3579
9 Halamish Str.
Caesarea (Ind. Park) 3088900
Israel

Product WatchPAT™One:
Device for diagnostic of obstructive sleep apnea syndrome

Model:	Classification:
12 WatchPAT ONE Devices • **WatchPAT ONE** • **WatchPAT ONE mobile application** • **zzzPAT s/w**	**IIa**
12 WatchPAT ONE E Devices • **WatchPAT ONE E (without chest sensor)** • **WatchPAT ONE mobile application** • **zzzPAT s/w**	**IIa**

Basic UDI-DI: 72901092221508008D

Conforming to Production Standards:

- **EN ISO 13485 : 2016**

Conforming to Product Standards:

- IEC 60601-1:2005+CPRR.1:2006+CORR.2:2007+AM1:2012
- IEC 60601-1-2:2014
- IEC 60601-1-11:2015
- IEC 62304:2006 + AMD1:2015
- IEC 60529 Ed 2.2 + COR2
- IEC 62366 : 2007 + A1:2014
- IEC 60601-1-6:2010 + A1:2013
- EN ISO 14971:2012

EC Declaration of Conformity – WatchPAT™ONE

- ISO 15223-1 : 2016
- PD IEC/TR 60878 : 2015
- ISO 7010:2019 (M002)
- EN 1041:2008 + A1:2013
- ISO 10993-1:2018
- ISO 80601-2-61:2011
- EU 207/2012
- RoHS Directive 2011/65/EU (RoHS2)

Appointed EU Authorized Representative:
Arazy Group GmbH
The Squaire 12, Am Flughafen,
60549 Frankfurt am Main, Germany

Full Name: Orit Kelner **Position:** QA Manager

Issued place: Itamar Medical Ltd., 9 Halamish Str. Caesarea (Ind. Park) 3088900, Israel

Date of issue: 11/5/2020 **Signature:** 

CE
2797