Declaration of Conformity

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CE 0473

REF

Oxygen Monitor
PM5900 Series

Classification: IIb

Classification criteria: Clause 3.2 Rule 10 of Annex IX of MDD

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II, 3 of the Directive 93/42/EEC and Directive 2007/47/EC on medical devices.

We certify that the production quality system conforms to the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed above.

Directives: General Application Directives: (MDD) Medical Device Directive, Council Directive 93/42/EEC Of 14 June 1993 Concerning Medical Devices, Directive 2007/47/EC Of The European Parliament.

Applied Standards:

EN 1041;2008	IEC 60601-1: Ed. 3.0:2005
ISO 80601-2-55:2011	IEC 60601-1-2 Ed. 4.0:2014
ISO 15001:2010	IEC 60601-1-6 Ed. 3.1b:2013
ISO 15223-1:2012	IEC 60601-1-8 Ed.2.0b:2007
EN ISO 14971:2012	IEC 60068-2-6 Ed. 7.0 b: 2007
IEC/TR 60878 Ed. 3.0 b: 2015	IEC 60068-2-27 Ed. 4.0 b: 2008
IEC 62366-1:2015	IEC 60068-2-64 Ed. 2.0 b: 2008

Notified Body: Intertek AMTAC Certification Services Limited CE 0473

Address: Davy Avenue Knowlhill Milton Keynes MK5 8NL, UK

Certification Registration No's: 1126 CE Date of Expiry: 03/August/2017

Devices already manufactured: SN traceability via Device History records

Validity of DOC: 04/August/2012 to Date of Expiry

Manufacture Representative: James Parker Signature: Digitally signed by James Parker Date: 2016.09.06 13:03:50 -04'00'

Position: Manager, Quality System/ISO Representative

Date of Issue: 04/August/2012