

Declaration of Conformity According to the Medical Devices Directive 93/42/EEC		
This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.		
Identification of the device(s) concerned	Vital Signs	
Device GMDN Code	63535	
Device CND Code	Z1203020282 (MULTI-PARAMETER PATIENT MONITORS – SOFTWARE)	
Device Basic UDI-DI	506075145VITALSIGNSFF (GS1 GMN)	
Device Risk Classification	Class IIa as per Rule 10 in Annex IX	
Identification of the Legal Manufacturer	Oxehealth Limited Magdalen Centre North The Oxford Science Park Oxford OX4 4GA	
Identification of Authorized Representative (EC REP)	Oxehealth AB c/o Bookwise & Co AB Tegelbaken 4a 111 52 Stockholm	
Applicable EC Certificates	Quality System Certificate Number	EC Quality System Certificate No. CE 633237 issued by Notified Body, BSI, Notified Body Number 2797
Date of first CE marking (using Notified Body 0086)	10th September 2018	
Relevant Harmonised Standards	ISO 13485:2016 IEC 62304:2006 + A1:2015 ISO 14971:2012	

Oxehealth Limited, Magdalen Centre North, The Oxford Science Park, Oxford, OX4 4GA, declare that Vital Signs conforms with the Essential Requirements of the European Medical Devices Directive 93/42/EEC Annex I as modified by 2007/47/EC and conformance assessment route in accordance with Annex II Section 3.2.

Signed for and on behalf of Oxehealth:

[I/S]

(Signature)

Oxford, UK
(Place of Issue)

Hugh Lloyd-Jukes

(Name)

CEO

(Job Title)

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(Date of Issue)