

EC DECLARATION OF CONFORMITY

Manufacturer's Name:	Bodystat Limited
Manufacturer's Address:	Ballakaap, Ballafletcher Road, Cronkbourne Douglas - Isle of Man IM4 4QJ
Manufacturer's Contact Details:	+44 1624 629 571
Manufacturer's Email Address:	info@bodystat.com
European Authorised Representative (EC REP):	Donawa Lifescience Consulting Srl
EC REP Address:	Piazza Albania, 10 00153 Rome, Italy
EC REP SRN (Single Registration Number):	IT-AR-000007785
Notified Body Name:	SGS Belgium
Notified Body Address:	SGS House Noorderlaan, 87 2030, Antwerp, Belgium.
Notified Body Identification Number:	1639
Name of Device:	BODYSTAT® 1500 Body Composition Monitoring Unit
Product Code:	0111T
Risk Class	Ila as per MDD 93/42/EEC Annex IX
GMDN (Global Medical Device Nomenclature) Code:	36022
Basic UDI-DI (issued by GS1 UK)	5060502140029
UDI format on labels:	Article code/UDI-DI: (01) - numeric, 13 digits. Serial Number: (21)- numeric, 6 digits. Date of Manufacture: (11) - YYYYMMDD, 8 digits. Example UDI: (01) 5060502140029 (21) 520008 (11) 20220304
Identification:	The Serial Number is visible on the hardware of the device and is accessible by the user.

Intended Purpose: Devices are used by professionals only in the health and medical environment and are not used by patients directly. The device is used to measure body composition and is not a diagnostic device. Results are for indication only and are not critical to the patient. Furthermore, the devices are non-invasive, non-hazardous and battery powered.

This declaration of conformity is issued under the sole responsibility of Bodystat Ltd.

This product is in conformity with the following Union harmonised legislation:

Directive 93/42/EEC as modified by the amending directive 2007/47/EC and is subject to procedures set out in Annex V of these directives.

Standards/Technical specifications used in relation to which conformity is declared:

Technical documentation required by the MDD (Annex VII) retained by Bodystat Limited.

Additional information and supporting documents:

EC Quality Systems Approval Certificate (Annex V) No. GB19/964625

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Signed: *Bryan Nooan*
Issued by: Bryan Nooan
Role: Managing Director

Issue Date: 25th April 2023