

UK Declaration of Conformity

MANUFACTURER
BODYSTAT Ltd. Chester House Main Road. Sulby IM7 2HJ Isle of Man

UK Responsible Person	UK Approved Body
Name: Psephos Limited Address: Sussex Innovation Centre, Science Park Square, Falmer, Brighton, Sussex, BN1 9SB, UK	Name: SGS United Kingdom Limited Address: Rossmore Business Park, Inward Way, Ellesmere Port, Cheshire, CH65 3EN. Number: 0120

PRODUCT IDENTIFICATION			
Intended Purpose	Product Models	Basic UDI-DI (issued by GS1 UK)	GMDN Code
Measure of body composition by using bio-electrical impedance principles <ul style="list-style-type: none">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.The devices are non-invasive, non-hazardous and battery powered.	Bodystat 500 Bodystat 1500 Bodystat 1500 MDD Bodystat Multiscan 5000 Bodystat Quadscan 4000	5060502141ZP	36022

The object of this declaration is in conformity with the technical provisions of the following UK legislation:
Medical Devices Regulations 2002 (SI 618) and subsequently amended by the EU Exit Regulation of 2019 (SI 719) and 2020 (SI 1478)

CONFORMITY ASSESSMENT		
The devices have been CE certified since 06 June 1999 by Notified Body SGS, with Notified Body number 1639 and UKCA certified since 25 April 2023 by SGS United Kingdom Ltd Approved Body 0120		
Device classification	Assessment Route	Standards applied
Class IIa	Part II of the UK MDR 2002, Annex V (as modified by Part II of Schedule 2A to the UK MDR 2002)	EMC: EN 60601-1-2 Safety: EN 60601-1 Risk Management: ISO 14971

Details of the samples tested and the versions of UK-recognized standards used to demonstrate conformity are documented in the Technical Documentation for the above devices. This Technical Documentation is maintained by Bodystat and available upon request from the relevant authorities.

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

Signed by: 
Role: Bryan Nooan
Managing Director & CEO

Place and date of issue: Sulby (Isle of Man)

01st August 2024