EC Declaration of Conformity

DOC-101
Rev. A

Revision History

CO#	Rev	Description of Change	Issue Date
01	00	New Release	12/12/2021

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We the Manufacturer:	The Biosparrow Inc, 1114 NW 131ST AVE PEMBROKE PINES, FL 33028, United States	
Product Name & Product Code	Product Name	Product Code
	Squegg	Squegg Version 1
Generic Indication(s):	Grip strength measurement	
In accordance with the following Directive and Classification:	We herewith declare that the above mentioned products meet the provisions of the following EC Council Directive 93/42/EEC of 14 June 1993 for medical devices. All supporting documents are retained under the premises of the manufacturer. The Company has been subjected to the procedures laid down in Annex II full quality assurance system, excluding section 4.	
Product Family:	Grip Strength Measuring Device	
Device Classification	**Product Name**	**Classification**
	Squegg	Class I - Rule 1 - Non-Invasive device, no other rule applies
Rule	Regulation (EU) 2017/745, Chapter V, Section 1, Article 51 & Annex VIII	
GMDN	**Product Name**	**GMDN Product Classification**
	Squegg	**33785 - Hand dynamometer/pinchmeter, electronic-** An electrically-powered instrument designed to assess neuromuscular function by measuring the force or power exerted by the muscles of the hand/forearm to squeeze/pinch an object. It is used to assess a patient's grip strength in clinical or research settings, typically as part of a rehabilitation program for geriatric patients or those who have suffered a stroke; it may in addition be designed to be used as part of an interactive rehabilitation system whereby forces applied by the patient translate to movements in a video-game. It includes a force transducer to translate force into electrical impulses for measurement.

The product is in conformity with the applicable requirements of the following documents:	Standard	Standard Title	EN Equivalent Standard
	EN-1041	Information Supplied by the Manufacturer with Medical Devices	EN 1041:2008
	ISO 14971	Medical Devices-Application of risk management to medical devices, with Amendment 1: Rationale for requirements	EN ISO 14971:2019
	ISO 10993-1	Biological Evaluation of Medical Devices	EN ISO 10993-1:2009
	EN ISO 13485:2016	Quality Management System for Medical Devices	EN ISO 10993-5:2009
	IEC 62366	Medical Devices - Application of Usability Engineering to Medical Devices	EN 62366:2008

Date CE Mark Affixed:	12/12/2021
Place:	1114 NW 131ST AVE,PEMBROKE PINES, FL 33028, United States

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The product complies with all applicable Essential Requirements of the Directives.

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Name	**Saket Gunjan**
Signature	saket gunjan
Position	**CEO**