



## UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No.

Issued To:

UKCA 766076 JTECH Medical Industries, Inc. 7633 S Main Building D Midvale Utah 84047 USA

In respect of:

Those aspects of Annex II relating to metrology of measuring devices used in the assessment of physical strength and flexibility.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: 2022-10-07

Date: 2022-10-07

Expiry Date: 2027-10-06

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000 Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK. A member of BSI Group of Companies.





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## **Supplementary Information to UKCA 766076**

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NBOG code	Device description	Intended purpose per IFU	
Class Im		AND A CONTRACT	
MD 1301 MDS 7010	Consoles		
	Receivers		
	Inclinometers		
	Dynamometers		
	Goniometers		
	Test End Switches	CN W GGARD	
MD 1111	Northstar software	Northstar software	

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## UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: UKCA 766076 Date: 2022-10-07 Issued To: JTECH Medical Industries, Inc. 7633 S Main Building D Midvale Utah 84047 USA

Date	Reference Number	Action
Current	3624095	Issued; Traceable to MDR 766074



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