The Keele Centre, Three Mile Lane, Keele, Staffordshire, ST5 5HH

Tel: +44 (0)844 800 4405 Fax: +44 (0)1782 444435

Email: info@metaphysis.co.uk

IO logo black

**Declaration of Conformity**

Metaphysis LLP declare that the products listed below comply with the General Safety and Performance Requirements and provisions of Medical Devices Regulations EU 2017/45

This compliance is self-certified under the supervision of the Competent Authority,

Health Products Regulatory Authority **​**Kevin O'Malley House  
Earlsfort Centre  
Earlsfort Terrace  
Dublin 2  
Ireland  
D02 XP77

**Class I**

**Part Numbers: 2-x-x**

**(for example 2-0-1FS, 2-0-1FL, 2-10-0 etc)**



Approved by: Date: 27/5/2021

Prof Peter J Ogrodnik

Position: Partner

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Tel: +44 (0)844 800 4405 Fax: +44 (0)1782 444435

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**Declaration of Classification**

METAPHYSIS LLP declare that the products listed below have been classified under Annex VIII of Medical Devices Regulations 2017/45

**Rule 1: (non-invasive)**

**Part Numbers**

**(for example 2-0-1FS, 2-0-1FL, 2-10-0 etc)**

Approved by: Date: 27/5/2021

Prof Peter J Ogrodnik

Position: Partner