Renishaw plc

New Mills, Wotton-under-Edge
Gloucestershire, GL12 8JR
United Kingdom

T +44 (0) 1453 524524
F +44 (0) 1453 524901
E uk@renishaw.com

www.renishaw.com

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Regulatory clarification statement

Ti RM1 powder

This statement is intended to clarify Renishaw's position on the CE marking of Ti RM1 Powder.

Renishaw does not apply the CE mark to Ti RM1 powder and therefore it will be the responsibility of the user to determine if the device that is being manufactured from the powder will need to be certified serperately.

Ti RM1 powder is a raw material which can be used to construct a finished medical device. Raw materials fall outside the definition of a medical device as per section 1.2a of the Medical Devices Directive 93/42/EEC (as amended) as they do not participate *directly* in the diagnosis, prevention, monitoring, treatment, or alleviation of any disease injury or handicap. This is affirmed by European Commission guidance (Med dev 2.1/1 – 'Definition of "medical devices" Definition of "accessory" Definition of "manufacturer"' section1.1b) that states medical devices are intended to be used for a medical purpose assigned by the manufacturer and the medical purpose relates in general to finished product meaning that the regulatory default is that raw materials are not medical devices.

On this basis Renishaw considers that the regulations apply to the finished device that is being made from the powder, the powder being a raw material, sold to a specification. The device made from the powder should be CE marked separately.

Signed..... **Dated.**21 July 2017.....

Jim Baker
Regulatory Affairs Manager
Healthcare Regulatory
Renishaw plc