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Product quality statement

1 June 2018

Dear Customer,

This document constitutes the product quality statement relative to the custom-made dental structures supplied by Renishaw, as referred to in the advice note with which products are delivered and in the Clinical and Laboratory Guidelines document which can be downloaded from the Renishaw website.

The statement is available in two forms, relative to advice notes issued respectively before or after 20 June 2012, which is the date when Renishaw extended its initial offering of tooth-supported dental structures (referred to as frameworks) to include implant-supported dental structures.

<u>For advice notes until 20 June 2012:</u>

Product quality statement

1) Frameworks for crowns and bridges that are designed by customers using a Renishaw Dental (or Procera® Forte) Scanner and incise CAD software are manufactured by Renishaw to fit patient models. Such design and manufacture are in accordance with the applicable essential requirements of the Medical Devices Directive (93/42/EEC) and the manufacture is carried out under a quality management system that complies with BS EN ISO 13485:2003.

2) Frameworks for crowns and bridges that are designed using scanners and/or CAD software other than those set out in (1) above are manufactured by Renishaw to customer-supplied designs. Such manufacture is in accordance with the applicable essential requirements of the Medical Devices Directive (93/42/EEC) and under a quality management system that complies with BS EN ISO 13485:2003.

For advice notes after 20 June 2012:

Product quality statement

"Structures" means the various types of finished or partially finished dental restorations supplied by Renishaw, including frameworks for crowns and bridges, and abutments.

1) Structures that are designed by customers using a Renishaw-supplied (or Procera® Forte) dental scanner and Renishaw-supplied CAD software are manufactured by Renishaw to fit patient models. Such design and manufacture are in accordance with the applicable essential requirements of the Medical Devices Directive (93/42/EEC) and the manufacture is carried out under a quality management system that complies with BS EN ISO 13485:2003*.

2) Structures that are designed using scanners and/or CAD software other than those set out in (1) above are manufactured by Renishaw to customer-supplied designs. Such manufacture is in accordance with the applicable essential requirements of the Medical Devices Directive (93/42/EEC) and under a quality management system that complies with BS EN ISO 13485:2003*.

* BS EN ISO 13485:2016 for structures manufactured after 6 May 2018.

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