

	<b>Declaration Number:</b>	<b>DC – 2019-01</b>
	<b>Manufacturer:</b>	<b>Wright Health Group Ltd Kingsway West, Dundee, DD2 3QD</b>
	<b>Product Family Name:</b>	<b>Polymer Teeth</b>
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	<b>Version:</b>	<b>3</b>
	<b>Date:</b>	<b>19.03.2019</b>

## Declaration

Wright Health Group Ltd hereby declares that the device specified above conforms with the Medical Device Directive - 93/42/EEC of June 14, 1993 as amended by Directive 2007/47/EC of 5 September 2007.

The stated products are designed and manufactured by Wright Health Group Ltd Limited, in accordance with the scope of a quality system which meets the requirements of ISO 13485:2016 and the Medical Devices Directive - 93/42/EEC of June 14, 1993 as amended by Directive 2007/47/EC of 5 September 2007.

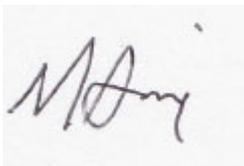
To ensure conformity with the provisions of the Directive applicable to Class I Medical Devices, Wright Health Group Ltd manufacture the devices specified in accordance with:

- BS EN ISO 22112 2017

**Product Codes, Descriptions and Variants are listed in the attached appendix**

This Declaration of Conformity is issued under the sole responsibility of the manufacturer

**Authorised By:**



**Quality Manager**  
**Date: 19/03/2019**