	Declaration Number:	DC – 2019-01
	Manufacturer:	Wright Health Group Ltd Kingsway West, Dundee, DD2 3QD
	Product Family Name:	Polymer Teeth
	Page:	Page 1 of 1
	Version:	3
	Date:	19.03.2019

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.

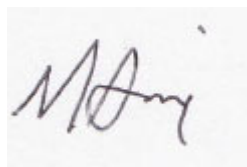
To ensure conformity with the provisions of the Directive applicable to Class I Medical Devices, Wright Health Group Ltd manufacture the devices specified in accordance with:

- 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