Declaration of Conformity

Application of Council Directive(s):	Medical Device Directive 93/42/EEC
Standards to which Conformity is Declared:	ISO 13485:2016, ISO 14971:2019, EN ISO 14971:2012, ISO 10993-1:2018, ISO 11137-1:2006, ISO 11137-2:2013, ISO 11607-1:2019, ISO 11607-2:2019, ISO 15223-1:2021, ISO 1797-1:2017, EN 1639:2009, ISO 3823-1:1997, ISO 3823-2:2003 AMD 1:2008, ISO 8325:2004, ISO 17664-1:2021, ISO 7711-1, CMDCAS and Swedish Regulation LVFS 2003:11
Manufacturer's Name:	SS White Burs, Inc.
Manufacturer's Address:	1145 Towbin Avenue, Lakewood, NJ 08701
Community Representative:	Obelis s.a. Bd. General Wahis 53 B-1030 Brussels, Belgium Phone:32.2.732.59.54 Fax: 32.2.732.60.03 Email: mail@obelis.net
Notified Body:	Intertek Semko AB, Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
ISO Certificate of Registration Number:	0087771-01
CE Certificate Number:	41315325-05
CE Certificate Issued Date:	9 February 2021
CE Mark Number:	0413
Type of Medical Device:	Carbide Dental Burs
Classification Rule:	Annex IX, Chapter III, Rule 6, Class IIa
Assessment Route:	Annex II Full Quality Assurance System
Model Numbers:	FG, RA, HP and Finishing, FGGW
Serial Numbers:	Various sizes

We hereby declare that the above mentioned devices comply with the European Medical Devices Directive 93/42/EEC as transposed into Swedish regulation LVFS 2003:11.

Management Representative:

Carmen Batista

Name: Carmen Batista
Title: QA/Regulatory Manager
Date: February 9, 2021