

DECLARATION OF CONFORMITY

Product: STAT/IM 2000 G4 Cassette Autoclave
Models: G4-152302, G4-152304, G4-152305, G4-152306
Basic UDI-DI: 764018507STATIM2000G4SV
Classification: Class IIa (MDR Annex VIII, Rule 16)
Legal Manufacturer: Dent4You AG
Bahnhofstrasse 2
9435 Heerbrugg Switzerland
SRN: *pending*
European Representative: Coltène/Whaledent GmbH + Co. KG
Raiffeisenstrasse 30
89129 Langenau Germany
SRN: DE-AR-000005719

We herewith declare that the above mentioned products meet the provisions of the following EC legislation/s and that Dent4You has exclusive responsibility of the content of this Declaration of Conformity. All supporting documentation is retained at the manufacturer's premises.

General Applicable Legislation:

Medical Device Regulation (EU) 2017/745 of 5 April 2017 on Medical Devices (MDR 2017/745, Annex IX Chapters I and III)
Low Voltage Directive: Directive 2014/35/EU of 26 February 2014
Electromagnetic Compatibility Directive: Directive 2014/30/EU of 26 February 2014
Restriction of Hazardous Substances Directive: Commission Delegated Directive (EU) 2015/863 of 31 March 2015

Standards and Common Specifications:

EN ISO 15223-1:2016; EN ISO 13485:2016, EN 61010-1:2010, EN 61010-2-040:2015, EN ISO 14971:2019, EN 62304:2006+A1:2015, EN 13060:2014+A1:2018, EN 61326-1:2013

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraß 65,
D-80339 München, Deutschland
Identification No. 0123
Certificate: G10 098596 0007
Date CE Mark was affixed: 2011-05-30
Date of Effectiveness of Product Under this Declaration: 2022-11-28
Place: Heerbrugg, Switzerland
Valid until: 2026-09-28
Signature: 
Date: 2022-11-28
Name & Title: Kelly Makimoto, PRRC