

## DECLARATION OF CONFORMITY

**Product:** STATIM 2000S Cassette Autoclave  
**Models:** 01-152302, 01-152304  
**Basic UDI-DI:** 764018507STATIM2000S2R  
**Classification:** Class IIa (MDR Annex IX, 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 Regulations: 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  
Ridlerstrasse 65,  
D-80339 München, Deutschland  
Identification No. 0123

**Certificate:** G10 098596 0007

**Date CE Mark was affixed:** 1998-03-24

**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