

DECLARATION OF CONFORMITY

Product family:	ASIL1906_Impression_Material
Intended Purpose:	AFFINIS is intended for the recording of the current physical situation in a patient's mouth ("dental impression material") for the purpose of repairing, reshaping or replacing the patient's teeth.
Medical Device Name:	AFFINIS
Basic UDI-DI:	76303929ASIL190613K
UMDNS /GMDN:	16-679 / 35866
EMDN:	Q010201
Classification:	Class IIa; (EU) 2017/745 Annex VIII, Rule 19 (3)
Legal Manufacturer:	Dent4You AG ¹ Bahnhofstrasse 2 9435 Heerbrugg Switzerland CHRN: CHRN-MF-20001009 SRN: CH-MF-000028926
European Representative:	Dent4You GmbH Raiffeisenstrasse 30 DE-89129 Langenau SRN: DE-AR-000006093

We herewith declare that the above-mentioned products meet the provisions of the following EC legislations and that Dent4You has exclusive responsibility for 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/EU, Annex IX excluding chapter II)

Standards and Common Specifications:

EN ISO 13485:2016, EN ISO 14971:2021, ISO 10993-1:2018, EN ISO 7405:2019, ISO 4823:2021

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65, D-80339 München, Deutschland Identification No. 0123
-----------------------	---

Certificate:	G10 098596 0007
---------------------	-----------------

¹ Manufacturing site: Colténe Whaledent AG, located at Feldwiesenstrasse 20, CH-9450, Switzerland.

REF	UDI-DI	Description
6501	07630243635115	AFFINIS light body 2 x 50ml
6580	07630243635122	AFFINIS light body Refill 20 x 50ml
6601	07630243635139	AFFINIS fast light body 2 x 50ml
6680	07630243635146	AFFINIS fast light body Refill 20 x 50ml
6511	07630243635153	AFFINIS regular body 2 x 50ml
6582	07630243635160	AFFINIS regular body Refill 20 x 50 ml
6611	07630243635177	AFFINIS fast regular body 2 x 50 ml
6682	07630243635184	AFFINIS fast regular body Refill 20 x 50 ml
6775	07630243635191	AFFINIS PRECIOUS light body Refill 2 x 50ml
6776	07630243635207	AFFINIS PRECIOUS regular body Refill 2 x 50ml
3851	07630243635214	AFFINIS PRECIOUS Trial Kit light body 1 x 50ml + regular body 1 x 50ml
6482	07630243635221	AFFINIS MonoBody System 360, 2 x 380ml
6547	07630243635238	AFFINIS MonoBody 2 x 75ml
6587	07630243635245	AFFINIS MonoBody Refill 20 x 75 ml
6485	07630243635252	AFFINIS heavy body System 360 Starter Kit, 1 x 380ml
6487	07630243635269	AFFINIS heavy body System 360, 2 x 380ml
6520	07630243635276	AFFINIS heavy body 2 x 75ml
6585	07630243635283	AFFINIS heavy body Refill 20 x 75ml
6620	07630243635290	AFFINIS fast heavy body 2 x 75ml
6685	07630243635306	AFFINIS fast heavy body Refill 20 x 75ml
60019554	07630243635313	AFFINIS heavy body BLACK EDITION 2 x 75 ml
60019776	07630243635320	AFFINIS heavy body BLACK EDITION System 360 Refill, 2 x 380 ml
6472	07630243635344	AFFINIS putty System 360 Single Pack, 2 x 380ml
6530	07630243635351	AFFINIS putty soft
6535	07630243635368	AFFINIS putty super soft
6531	07630243635375	AFFINIS fast putty soft

Place: Altstaetten, Switzerland

Valid to: 28/09/2026



PRRC Coltene AG / D4Y
19 Feb 2025

Signature:

Advanced electronic signature

Date: 2025-02-19

Name & Title: Patrick Vortanz PRRC