

EG Konformitätserklärung für Medizinprodukte
EC Declaration of Conformity for medical devices

Nach Anhang VII der EG Richtlinie für Medizinprodukte 93/42/EWG
According to annex VII of the Directive for medical devices 93/42/EEC

Hersteller/*Manufacturer:* Coltène/Whaledent AG
Adresse/*Address:* Feldwiesenstrasse 20
CH-9450 Altstätten

Wir erklären hiermit, dass das Produkt in alleiniger Verantwortung
Herewith we declare under our sole responsibility that the product

Produktname
product name klassifiziert nach Anhang IX
der Richtlinie 93/42/EWG
classified according to annex IX
Directive 93/42/EEC

Affinis Klasse/class **I**

UMDNS / GMDN codes: 16-679 / 35866

den einschlägigen Bestimmungen der nachfolgenden Richtlinie
complies with the relevant regulations of the following directive

Richtlinie 93/42/EWG vom 14. Juni 1993 über Medizinprodukte
Directive 93/42/EEC of June 14, 1993 for medical devices


und deren Umsetzung in nationale Gesetze entspricht.
and with the national laws adopted by Member States.

Konformitätserklärung ist gültig in Verbindung mit der Berichtigung C 2 (27.12.2019) der MDR 2017/745, gültig bis: 2024-05-25
Declaration of Conformity is valid in combination with the corrigendum C 2 (27.12.2019) the MDR 2017/745, valid till: 2024-05-25

Anhang/Annex I: Liste der angewandten Normen / List of applied standards
Anhang/Annex II: Detaillierte Produkteliste / Detailed list of products

Ausgabedatum / *Date of issue*

Altstätten, 25.05.2021


Martin Schaufelberger
General Manager Coltène/Whaledent AG / CEO Coltene Group
Name und Unterschrift des Befugten
Name and signature of authorized person

Anhang I / Annex I :

Affinis

Standard number and year:	EN ISO 4823
Standard name:	Dentistry – Elastomeric impression materials

Anhang II / Annex II :

Affinis	
REF	Beschreibung/Description
6471	AFFINIS putty System 360 Starter Kit, 1 x 380 ml
6472	AFFINIS putty System 360 Single Pack, 2 x 380 ml
6480	AFFINIS MonoBody System 360 Starter Kit, 1 x 380 ml
6482	AFFINIS MonoBody System 360, 2 x 380 ml
6485	AFFINIS heavy body System 360 Starter Kit, 1 x 380 ml
6487	AFFINIS heavy body System 360, 2 x 380 ml
6500	AFFINIS light body microSystem 4 x 25 ml
6501	AFFINIS light body 2 x 50 ml
6510	AFFINIS regular body microSystem 4 x 25 ml
6511	AFFINIS regular body 2 x 50 ml
6520	AFFINIS heavy body 2 x 75 ml
6530	AFFINIS putty soft
6531	AFFINIS fast putty soft
6535	AFFINIS putty super soft
6547	AFFINIS MonoBody 2 x 75 ml
6575	AFFINIS light body microSystem 20 x 25 ml
6577	AFFINIS regular body microSystem 20 x 25 ml
6580	AFFINIS light body Refill 20 x 50 ml
6582	AFFINIS regular body Refill 20 x 50 ml
6585	AFFINIS heavy body Refill 20 x 75 ml
6587	AFFINIS MonoBody Refill 20 x 75 ml
6590	AFFINIS heavy body 2 x 50 ml
6595	AFFINIS heavy body Refill 20 x 50 ml
6600	AFFINIS fast light body microSystem 4 x 25 ml
6601	AFFINIS fast light body 2 x 50 ml
6610	AFFINIS fast regular body microSystem 4 x 25 ml
6611	AFFINIS fast regular body 2 x 50 ml
6620	AFFINIS fast heavy body 2 x 75 ml
6650	AFFINIS fast heavy body 2 x 50 ml
6652	AFFINIS fast heavy body Refill 20 x 50 ml
6675	AFFINIS fast light body microSystem 20 x 25 ml
6677	AFFINIS fast regular body microSystem 20 x 25 ml
6680	AFFINIS fast light body Refill 20 x 50 ml
6682	AFFINIS fast regular body Refill 20 x 50 ml
6685	AFFINIS fast heavy body Refill 20 x 75 ml
6775	AFFINIS PRECIOUS light body Refill 2 x 50 ml
6776	AFFINIS PRECIOUS regular body Refill 2 x 50 ml
6779	AFFINIS PRECIOUS light body microSystem 4 x 25 ml
6780	AFFINIS PRECIOUS regular body microSystem 4 x 25 ml
60019554	AFFINIS heavy body BLACK EDITION 2 x 75 ml

Affinis	
REF	Beschreibung/Description
60019774	AFFINIS heavy body BLACK EDITION System 360 Starter Kit, 1 x 380 ml
60019776	AFFINIS heavy body BLACK EDITION System 360 Refill, 2 x 380 ml
60022176	AFFINIS Starter Kit BLACK EDITION