COLTENE

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

PRESIDENT The Original

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, 6.5.21

Roland Streuf
Director RA/Q, Quality Control & Analytics

Name und Unterschrift des Befugten
Name and signature of authorized person

Anhang I / *Annex I* :

PRESIDENT The Original

Standard number and year:	EN ISO 4823:2015
Standard name:	Dentistry – Elastomeric impression materials

Anhang II / *Annex II* :

PRESIDENT The Original	
REF	**Beschreibung/*Description***
60019932	PRESIDENT The Original Xtra light body microSystem 4 x 25 ml
60019933	PRESIDENT The Original light body microSystem 4 x 25 ml
60019934	PRESIDENT The Original light body microSystem 20 x 25 ml
60019935	PRESIDENT The Original regular body microSystem 4 x 25 ml
60019936	PRESIDENT The Original regular body microSystem 20 x 25 ml
60019937	PRESIDENT The Original Xtra light body 2 x 50 ml
60019938	PRESIDENT The Original light body 2 x 50 ml
60019939	PRESIDENT The Original regular body 2 x 50 ml
60019940	PRESIDENT The Original heavy body 2 x 50 ml
60019941	PRESIDENT The Original heavy body 2 x 75 ml
60019942	PRESIDENT The Original putty 2 x 300 ml
60019943	PRESIDENT The Original putty soft 2 x 300 ml
60019944	PRESIDENT The Original putty super soft 2 x 300 ml
60019945	PRESIDENT The Original MonoBody System 360 Starter Kit, 1 x 380 ml
60019946	PRESIDENT The Original MonoBody System 360 Refill, 2 x 380 ml
60019947	PRESIDENT The Original heavy body System 360 Starter Kit, 1 x 380 ml
60019948	PRESIDENT The Original heavy body System 360 Refill, 2 x 380 ml
60019949	PRESIDENT The Original light body 2 x 53 ml
60019950	PRESIDENT The Original regular body 2 x 53 ml
60021899	PRESIDENT The Original Trial Kit Xtra Light Body + Light Body
60021947	PRESIDENT The Original putty super soft 2 x 150 ml
60021952	PRESIDENT TO Xtra light body 1x50ml
60021985	PRESIDENT TO putty soft 2x150ml
60021986	PRESIDENT TO putty 2x150ml
60022166	PRESIDENT The Original fast putty soft 2 x 300 ml
60022173	PRESIDENT TO Trial Pack lb rb