COLTENE

EG Konformitätserklärung für Medizinprodukte
EC Declaration of Conformity for medical devices

Konformitätsbewertungsverfahren nach der Verordnung über Medizinprodukte 2017/745/EG,
Conformity Assessment Procedure according to the Regulation for medical devices 2017/745/EU

Hersteller/*Manufacturer*:	**Coltène/Whaledent AG**
Adresse/*Address:*	Feldwiesenstrasse 20 9450 Altstätten SWITZERLAND
CHRN	CHRN-MF-20000015
SRN	Nummer noch nicht verfügbar/ *Number not yet available*
Europäischer Bevollmächtigter/European Responsible	**Coltène/Whaledent GmbH + Co. KG** Raiffeisenstraße 30 89129 Langenau GERMANY
SRN	DE-AR-000005719

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

Produktkategorie/Product Category	**ACCESSORY**
Produktgruppe/ Product Group	**Mixing Tips**
Produktfamilie/Product Family	**ACCE2001_Mixing Tips**
Produktname/ Product Name (Brand)	**Mixing Tips** **Universal Mixing Tips** **Dynamic Mixing Tips** **Oral Tips** **Spreader Tips**
UMDNS codes GMDN codes	15-590_Mixers 58399 Dental material mixing nozzle, non-sterile
CND- Code	Q010506 SPINGIPASTA MONOUSO (DENTAL PASTE APPLICATORS, SINGLE-USE)
Basis UDI-DI/ *Basic UDI DI*	764018147COLT5B6 764018147COLT6B8 764018147COLT7BA
Zweckbestimmung / *intended purpose*	The mixing tips are intended for mixing and precise intraoral application of two-component dental materials from cartridges. The non-sterile, single-use devices are designed to mix two inactive compounds together during a dental procedure, which may be applied directly into the oral cavity / tooth of the patient; or also for other dental applications.
klassifiziert nach Anhang VIII der Verordnung 2017/745/EG *classified according to Annex VIII Regulation 2017/745/EG*	**Klasse/class I** Regel/*rule* 5(1)

allen anwendbaren Anforderungen der MDR Verordnung 2017/745/EU entspricht und somit dessen Konformität mit dieser Verordnung.
complies with all applicable requirements of MDR Regulation 2017/745/EU and thus its conformity to this Regulation.

Konformitätserklärung ist gültig bis: 2024-03-15
Declaration of Conformity is valid until: 2024-03-15

COLTENE

Ausgabedatum / *Date of issue:*
Altstätten,

2.6.21

Roland Streuf
Director Regulatory & Quality/
Person Responsible for Regulatory Compliance

Martin Schaufelberger
CEO COLTENE Group, Group Management

Table 1: Scope

Ref. Nr	Description (SAP)
60019663	Universal Mixing Tip, 40pcs
60019694	Universal Mixing Tip, 100pcs
6550	Mixing Tip Yellow, 40pcs
6552	Mixing Tip Turquoise, 40pcs
6747	Mixing Tip Brown Short SFine, 40pcs
6748	Mixing Tip Brown Pointed, 40pcs
6749	Mixing Tip Brown Long Fine, 40pcs
6759	Mixing Tip Brown Short Fine, 40pcs
7774	Mixing Tip Blue Pointed, 40pcs
6162	DYNAMIC MIXING TIP YELLOW, 40pcs
6163	SYS360 FIXATION RING YELLOW, 1pcs
6210	ORAL TIP WHITE, 100pcs
6223	SPREADER TIP, 100 pcs
6555	ORAL TIP YELLOW, 100pcs