

Material Component Data Sheet (MCDS)

11.2 Arti Pink Bite Wax

F_EW027; Rev.: 001

Section I: Product Classification	
Identity / REF	As used on Label, Price List, Catalogue
REF-Code	BK 6006, BK 6016, BK 6017, BK 6018
Trade Name	Bausch Arti-Pink Bite Wax X-Hard 3,00 mm
Classification Register	GMDN: A dental material (modelling wax) delivered as bite rim wax, plate prefabricated plates of wax with or without reinforcing foils (metal, polymer) for registration of jaw relation (making bite rims). EMDN: Q010203 Dental Waxes
Basic-UDI-DI / Basis-UDI-DI:	++E210ARTIPINKBITEW5D
Classification / Klassifizierung:	Class I / Klasse I
Classification (MDR)	Regulation (EU) 2017/745 (MDR), Annex VIII, Invasive devices, Rule 5: “All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active medical device or which are intended for connection to a class I active device are classified as: - class I if they are intended for transient use;”
Conformity assessment procedure / Konformitätsbewertungsverfahren:	The conformity assessment procedure complies with Article 52, (7) of the Regulation (EU) 2017/745 (MDR) [Article 19 as well as Annexes II & III].
Description of Product / Intended Use	Arti-Pink ist ein intraorales Bissregistrierungsmaterial auf Basis von Parafin-Wachsen. - Zweckbestimmung: Analoge Bestimmung der Ober-/Unterkieferrelation im Gebiss des Patienten ab dem 15. Lebensjahr [Bissregistrierung] (zur vorübergehenden Anwendung). Die Anwendung ist ausschließlich für Zahnärzte bestimmt. - vorgesehenes Körperteil: Mundhöhle, zwischen Ober- und Unterkieferzahnreihen - Funktionsweise/Physikalisches Prinzip: 1:1-Wiedergabe der Okklusionsverhältnisse aufgrund mechanischer, form-schlüssiger Verdrängung des Materials durch die Zähne. Arti-Pink is an intraoral bite registration material based on paraffin waxes. - Intended use: Analogous determination of the upper/lower jaw relationship in the patient's dentition from the age of 15 [Bite registration] (for temporary use). The application is intended exclusively for dentists. - Intended body part: Oral cavity, between the upper and lower rows of teeth - Functional/physical principle: 1:1 reproduction of occlusal conditions due to mechanical, form-fit displacement of the material by the teeth.

Section II: Manufacturer 	
Manufacturer's Name	Dr. Jean Bausch GmbH & Co.KG
Manufacturer's Address	Oskar-Schindler-Str.4
Emergency Phone	+49 221 70936 20
Date of issuance	2024-03-30
E-mail	pb@bauschdental.de
Web	www.bauschdental.de

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Section III: Authorized representative		EC	REP
Representative Name	n.a.		
Representative Address	n.a.		
Emergency Phone	n.a.		
Date of issuance	n.a.		
E-mail	n.a.		
Web	n.a.		

Section IV: Technical and Chemical Data					
Ingredients/Material	CAS-No.	EC / List no.	COLOR-Index-No	Part of Composition Base	Part of Composition Catalyst
Paraffin-Wachs	8002-74-2	232-315-6	n.a.	65%	n.a.
Pentaester/ Harzsäuren	221354-73-0	606-939-8	n.a.	25%	n.a.
Polyethylenwachs	9002-88-4	200-815-3	n.a.	10%	n.a.
Tropal Wachs Farbe	k.a.	k.a.	k.a.	< 0,01 %	

Odor and Chemical Description	No odor
Safety Instructions	Medical Product – For professional use only.
Comments	All active ingredients used in our formulations are safe in those quantities exposed to the patient. All components in the formulation are mixed into two main components according to the intended purpose. A chemical reaction takes place via the catalyst, which causes the two main components to react to form an inert silicone mass. This set mass is completely harmless to the patient and the user within the scope of the intended use. The potential risk using these products has been evaluated in the Risk Analysis (ISO 14971:2012) and the biological safety (ISO 10993-1:2020) standards.
Signature of Company Safety Officer	Peter Bausch 