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Approval

Owner Role	Sign-off By	Sign-off Date	
2100-Document Owner Zhermack Export Document Owner	Claudia Bertarelli	16-Apr-2025 12:34 pm	GMT

See Annex I for translations / Voir « Annex I » pour les traductions / Se bilag I for oversættelse/ Siehe Anhang I für die Übersetzung/ Skatiet I pielikumu tulkošanai/ Zobacz załącznik I dla tłumaczenia/ Glej Prilogo I za prevod/ Çeviri için Ek I'e bakın

Manufacturer:	ZHERMACK S.p.A trading as ZK SPA trading as ZRK SPA trading as ZAC SPA via Bovazecchino 100 45021 Badia Polesine (RO), Italy Single registration number (SRN): IT-MF-000011215
Authorized EU-representative:	Not applicable
Authorized UK-representative:	Dentsply IH Limited Brunel Way, Stonehouse, Gloucestershire, GL10 3GB

PRODUCT CODE / CATALOGUE NUMBER	NAME	PRODUCT CODE / CATALOGUE NUMBER	NAME
C203090	ELITE HD+ LIGHT BODY FAST SET	C207003	HYDRORISE EXTRA LIGHT BODY FAST SET
C203040	ELITE HD+ LIGHT BODY FAST SET	C207002	HYDRORISE EXTRA LIGHT BODY NORMAL SET
C203030	ELITE HD+ LIGHT BODY NORMAL SET	C207090	HYDRORISE IMPLANT HEAVY BODY
C203035	ELITE HD+ LIGHT BODY NORMAL SET	C207096	HYDRORISE IMPLANT MEDIUM BODY
C202360	ELITE HD+ MAXI PUTTY SOFT FAST SET	C207095	HYDRORISE IMPLANT KIT HEAVY/LIGHT
C202370	ELITE HD+ MAXI PUTTY SOFT FAST SET	C207091	HYDRORISE IMPLANT LIGHT BODY
C202340	ELITE HD+ MAXI PUTTY SOFT NORMAL SET	C207092	HYDRORISE IMPLANT MEDIUM BODY
C202320	ELITE HD+ MAXI TRAY MATERIAL FAST SET	C207126	HYDRORISE IMPLANT MEDIUM BODY
C202330	ELITE HD+ MAXI TRAY MATERIAL FAST SET	C207122	HYDRORISE IMPLANT MEDIUM BODY
C202020	ELITE HD+ MONOPHASE NORMAL SET	C207001	HYDRORISE LIGHT BODY FAST SET
C203091	ELITE HD+ PUTTY SOFT FAST SET	C207000	HYDRORISE LIGHT BODY NORMAL SET
C203092	ELITE HD+ PUTTY SOFT NORMAL SET	C207043	HYDRORISE MAXI HEAVY BODY FAST SET
C203025	ELITE HD+ REGULAR BODY NORMAL SET	C207063	HYDRORISE MAXI HEAVY BODY FAST SET
C203020	ELITE HD+ REGULAR BODY NORMAL SET	C207042	HYDRORISE MAXI HEAVY BODY NORMAL SET
C203127	ELITE HD+ KIT	C207041	HYDRORISE MAXI MONOPHASE FAST SET
C203050	ELITE HD+ SUPER LIGHT BODY FAST SET	C207040	HYDRORISE MAXI MONOPHASE NORMAL SET
C202032	ELITE HD+ TRAY MATERIAL FAST SET	C207045	HYDRORISE MAXI PUTTY FAST SET
C203010	ELITE HD+ PUTTY SOFT FAST SET	C207065	HYDRORISE MAXI PUTTY FAST SET
C203012	ELITE HD+ PUTTY SOFT FAST SET	C207044	HYDRORISE MAXI PUTTY NORMAL SET
C203000	ELITE HD+ PUTTY SOFT NORMAL SET	C207007	HYDRORISE MONOPHASE FAST SET
C203002	ELITE HD+ PUTTY SOFT NORMAL SET	C207006	HYDRORISE MONOPHASE NORMAL SET
C300110	FREEALGIN	C207011	HYDRORISE PUTTY FAST SET
C300105	FREEALGIN MAXI EXTRA FAST	C207013	HYDRORISE PUTTY FAST SET
C300106	FREEALGIN MAXI EXTRA FAST	C207010	HYDRORISE PUTTY NORMAL SET
60578333	AQUASIL PUTTY HARD ECOPACK	C207012	HYDRORISE PUTTY NORMAL SET
60578332	AQUASIL PUTTY HARD FAST STD.PACK	C207005	HYDRORISE REGULAR BODY FAST SET
60578321	AQUASIL PUTTY SOFT ECOPACK	C207004	HYDRORISE REGULAR BODY NORMAL SET
60578320	AQUASIL PUTTY SOFT REG STD.PACK	C207071	HYDRORISE MINI KIT

Classification and Rules (EU and UK)	EU class: Class IIa following Rule 19 ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745 UK Class: Class I following Rule 5 ACCORDING TO ANNEX IX OF THE DIRECTIVE 93/42/EC AND UK MDR 2002
Basic UDI-DI :	805600037VPS0BD

EMDN code / description :	Q01020102 – A-Silicone dental Impression
GMDN code / description :	35866 – A-Silicone dental Impression material
Intended purpose:	A-Silicone dental Impression material
WE HEREWITH DECLARE, UNDER OUR SOLE RESPONSIBILITY, THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF - THE REGULATION EU/2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEXES IX CHAPTER I and III. - UKMDR2002: THE MEDICAL DEVICE REGULATIONS 2002 (SI 618) as subsequently amended by the EU EXIT REGULATIONS OF 2019 (SI 791) and 2020 (SI 1478). ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.	
External references (Common Specifications, Standards, Regulations) applied	2100-LOAER-003 Common specification: N/A
EC Certificate	EC certificate number: G100536180028 Rev.02 Notified Body name: TÜV SÜD Product Service GmbH Notified Body address: Ridlerstrasse 65,80339 München - Germany Notified Body ID: 0123 Certificate expiration date: 20.10.2026
UK Certificate	Not applicable
Reference to the corresponding Technical Documentation	Not applicable

Badia Polesine, 16/04/2025

Baruzzo Barbara
Sr. QA Manager

Zhermack S.p.A.

Annex I - Translation

Traduction / Oversættelse / Übersetzung / Tulkojums / Tłumaczenie / Prevajanje / Çeviri

EN	FR / DK / DE / LV / PL / SI / TR
Manufacturer	Fabricant / Producent / Hersteller / Ražotājs / Producent / Proizvajalec / Üretici
Name of the site	Nom du site / Stedets navn / Name des Standorts / Objekta nosaukums / Nazwa ośrodka / Naziv lokacije / Tesisin adı
Address of the site	Adresse du site / Stedets adresse / Anschrift des Standorts / Objekta adrese / Adres ośrodka / Naslov lokacije / Tesisin adresi
Single registration number (SRN)	Numéro d'enregistrement unique (SRN) / Individuelt registreringsnummer (SRN-nummer) / Einmalige Registrierungsnummer (SRN) / Vienotais reģistrācijas numurs (VRN) / Numer pojedynczej rejestracji (SRN) / Enotna registrska številka (SRN) / Tek kayıt numarası (SRN)
Authorized EU-representative	Représentant européen autorisé / Autoriseret EU-repræsentant / In der EU ansässiger Bevollmächtigter / Pilnvarotais pārstāvis ES / Autoryzowany przedstawiciel UE / Pooblaščeni predstavnik EU / Yetkili AB temsilcisi
Classification and Rules (EU)	Classification et Règles (UE) / Klassificering og regler (EU) / Klassifizierung und Regeln (EU) / Klasifikācija un noteikumi (ES) / Klasyfikacja i reguły (UE) / Razvrstitev in pravila (EU) / Sınıflandırma ve Kurallar (AB)
EU class	Classe de l'UE / EU-klasse / EU-Klasse / ES klase / Klasa UE / Razred EU / AB sınıfı:
ACCORDING TO ANNEX VIII OF THE REGULATION 2017/745	CONFORMÉMENT À L'ANNEXE VIII DU RÈGLEMENT 2017/745 I HENHOLD TIL BILAG VIII TIL FORORDNING 2017/745 GEMÄSS ANHANG VIII DER VERORDNUNG 2017/745 SASKAŅĀ AR REGULAS 2017/745 VIII PIELIKUMU ZGODNIE Z ANEKSEM VIII DO ROZPORZĄDZENIA 2017/745 V SKLADU S PRILOGO VIII K UREDBI 2017/745 2017/745 SAYILI YÖNETMELİĞİN EK VIII'SİNE GÖRE
Basic UDI-DI	IUD-ID de base / Grundlæggende UDI-DI / Grundlegende UDI-DI/Pamata UDI-DI /Kod Basic UDI-DI/Osnovni UDI-DI/Temel UDI-DI
EMDN code - description	Code EMDN – Description / EMDN-kode - beskrivelse / EMDN-Code - Beschreibung / EMDN kods - apraksts / Kod EMDN - opis / EMDN koda - opis / EMDN kodu - açıklaması
GMDN code - description	Code GMDN - Description / GMDN-kode - beskrivelse / GMDN-Code - Beschreibung / GMDN kods - apraksts / Kod GMDN - opis / GMDN koda - opis / GMDN kodu - açıklaması
Intended purpose	Utilisation prévue / Tilsigtet anvendelse / Vorgesehener Verwendungszweck / Paredzētais nolūks / Przeznaczenie / Predvideni namen / Kullanım amacı
WE HEREWITH DECLARE, UNDER OUR SOLE RESPONSIBILITY, THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF - THE REGULATION EU/2017/745 ON MEDICAL DEVICES, IN ACCORDANCE WITH THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEXES IX CHAPTER I and III. (or ANNEXE X or ANNEXE XI – precise chapters) ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.	NOUS DÉCLARONS PAR LA PRÉSENTE, SOUS NOTRE SEULE RESPONSABILITÉ, QUE LES PRODUITS SUSMENTIONNÉS SATISFONT AUX DISPOSITIONS - DU RÈGLEMENT UE/2017/745 RELATIF AUX DISPOSITIFS MÉDICAUX, CONFORMÉMENT À LA PROCÉDURE D'ÉVALUATION DE LA CONFORMITÉ. TOUTES LES PIÈCES JUSTIFICATIVES SONT CONSERVÉES DANS LES LOCAUX DU FABRICANT. LE FABRICANT EST EXCLUSIVEMENT RESPONSABLE DE LA DÉCLARATION DE CONFORMITÉ. VI ERKLÆRER HERMED PÅ EGET ANSVAR, AT OVENNÆVNTE PRODUKTER OPFYLDER BESTEMMELSERNE I - FORORDNING EU/2017/745 OM MEDICINSK UDSTYR I OVERENSSTEMMELSE MED DEN OVERENSSTEMMELSESVURDERINGSPROCEDURE, DER ER BESKREVET. AL UNDERSTØTTENDE DOKUMENTATION OPBEVARES HOS PRODUCENTEN. PRODUCENTEN ER EKSKLUSIVT ANSVARLIG FOR OVERENSSTEMMELSESERKLÆRINGEN. WIR ERKLÄREN HIERMIT IN ALLEINIGER VERANTWORTUNG, DASS DIE OBEN GENANNTEN PRODUKTE DEN BESTIMMUNGEN DER - VERORDNUNG EU/2017/745 ÜBER MEDIZINPRODUKTE ENTSPRECHEN, GEMÄSS DEN VERFAHREN ZUR KONFORMITÄTSBEWERTUNG. ALLE UNTERSTÜTZENDEN DOKUMENTE WERDEN AM STANDORT DES HERSTELLERS AUFBEWAHRT. DIE VERANTWORTUNG FÜR DIE KONFORMITÄTSERKLÄRUNG LIEGT AUSSCHLIESSLICH BEIM HERSTELLER MĒS AR ŠO VIENĪGI UZ SAVU ATBILDĪBU APLIECINĀM, KA IEPRIEKŠ MINĒTIE RAŽOJUMI ATBILST NOTEIKUMIEM, KAS PAREDZĒTI - REGULĀ ES/2017/745, KAS ATTIECAS UZ MEDICĪNISKĀM IERĪCĒM, SASKAŅĀ AR ATBILSTĪBAS NOVĒRTĒŠANAS PROCEDŪRU. VISA APLIECINOŠĀ DOKUMENTĀCIJA TIEK GLABĀTA RAŽOTĀJA TELPĀS. PAR ATBILSTĪBAS DEKLARĀCIJU IR ATBILDĪGS TIKAI UN VIENĪGI RAŽOTĀJS.

	NA NASZĄ WYŁĄCZNĄ ODPOWIEDZIALNOŚĆ NINIEJSZYM ZAŚWIADCZAMY, ŻE WYŻEJ WYMIENIONE PRODUKTY SPEŁNIAJĄ WYMAGANIA OKREŚLONE W POSTANOWIENIACH - ROZPORZĄDZENIA UE/2017/745 W SPRAWIE WYROBÓW MEDYCZNYCH ZGODNIE Z PROCEDURĄ OCENY ZGODNOŚCI. CAŁOŚĆ POWIĄZANEJ DOKUMENTACJI JEST PRZECHOWYWANA PRZEZ PRODUCENTA. WYŁĄCZNĄ ODPOWIEDZIALNOŚĆ ZA DEKLARACJĘ ZGODNOŚCI PONOSI PRODUCENT. NA LASTNO ODGOVORNOST IZJAVLJAMO, DA ZGORAJ NAVEDENI IZDELKI IZPOLNJUJEJO DOLOČBE - UREDBA EU/2017/745 O ZDRAVSTVENIH PRIPOMOČKIH, V SKLADU S POSTOPKOM OCENJEVANJA SODOBNOSTI. VSO DOKAZNO DOKUMENTACIJO HRANI PROIZVAJALEC. ZA IZJAVO O SKLADNOSTI JE ODGOVOREN IZKLJUČNO PROIZVAJALEC. YUKARIDA BELİRTİLEN ÜRÜNLERİN AB/2017/745 SAYILI TIBBİ CİHAZLAR YÖNETMELİĞİ HÜKÜMLERİNE UYGUN OLDUĞUNU, - EKLERDE AÇIKLANAN UYGUNLUK DEĞERLENDİRME PROSEDÜRÜNE UYGUN OLARAK. TÜM DESTEKLEYİCİ BELGELER ÜRETİCİNİN TESİSLERİNDE SAKLANMAKTADIR. UYGUNLUK BEYANINDAN MÜNHASIRAN ÜRETİCİ SORUMLUDUR.
External references (Common Specifications, Standards, Regulations) applied	Références externes (Spécifications, Normes, Règlements communs) appliquées Anvendte eksterne referencer (fælles specifikationer, standarder, forordninger) Angewandte externe Referenzen (gemeinschaftliche Spezifikationen, Normen, Verordnungen) Piemērotās ārējās atsauces (kopējās specifikācijas, standarti, noteikumi) Zastosowane odniesienia zewnętrzne (wspólne specyfikacje, normy, rozporządzenia) Uporaba zunanjih referenc (skupne specifikacije, standardi, predpisi) Uygulanan dış referanslar (Ortak Şartnameler, Standartlar, Yönetmelikler)
EC Certificate	Certificat CE / EF-certifikat / EG-Zertifikat / EK sertifikāts / Certyfikat EC / Certifikat ES / EC Belgesi
EC certificate number	Numéro de certificat CE / EF-certifikatnummer / EG-Zertifikatsnummer / EK sertifikāta numurs / Numer certyfikatu EC / Številka certifikata ES / EC belge numarası
Notified Body name	Nom de l'Organisme notifié / Navn på bemyndiget organ / Benannte Stelle / Paziņotās iestādes nosaukums / Nazwa organu notyfikowanego / Naziv priglašenega organa / Onaylanmış Kuruluş adı
Notified Body address	Adresse de l'Organisme notifié / Det bemyndigede organs adresse / Anschrift der benannten Stelle / Paziņotās iestādes adrese / Adres organu notyfikowanego / Naslov priglašenega organa/ Onaylanmış Kuruluş adresi
Notified Body ID	Identifiant de l'Organisme notifié / Det bemyndigede organs id / Kennnummer der benannten Stelle / Paziņotā iestādes Nr / Identyfikator organu notyfikowanego / ID priglašenega organa / Onaylanmış Kuruluş Kimliği
Certificate expiration date	Date d'expiration du certificat /Certifikatets udløbsdato / Ablaufdatum des Zertifikats / Sertifikāta derīguma termiņš / Data ważności certyfikatu / Datum izteka veljavnosti potrdila / Belge son geçerlilik tarihi
Reference to the corresponding Technical Documentation	Référence à la Documentation Technique correspondante / Henvisning til den tilsvarende tekniske dokumentation / Verweis auf die entsprechende Technische Dokumentation / Atsauce uz attiecīgo tehnisko dokumentāciju / Odniesienie do odpowiedniej dokumentacji technicznej / Sklic na ustrezno tehnično dokumentacijo / İlgili Teknik Doküm antasyona Referans
Technical Documentation name	Nom de la Documentation Technique / Navn på teknisk dokumentation / Bezeichnung der Technischen Dokumentation / Tehniskās dokumentācijas nosaukums / Naziv tehnične dokumentacije
Technical Documentation Index	Index de la Documentation Technique / Indeks for teknisk documentation / Index der Technischen Dokumentation / Tehniskās dokumentācijas indekss / Nazwa dokumentacji technicznej / Indeks dokumentacji technicznej / Indeks tehnične dokumentacije / Teknik Dokümantasyon adı / Teknik Dokümantasyon Dizini

REVISION HISTORY

REVISION LEVEL	PREPARED BY	DESCRIPTION OF CHANGE
0	Francesca Bottaro	First release and replace of Aquasil Putty dedicated declaration of conformity
1	Francesca Bottaro	Update of the template, product list and UK AR address
2	Francesca Bottaro	Correction of typo in product name