

## EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

We hereby declare that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer and the below mentioned products meet the provisions of the EU Regulation above. All supporting documentation is retained on the premises of the manufacturer and the Notified Body.

<b>Product(s)</b>	<b>ProBase Cold, ProBase Cold Clear</b>
<b>Basic-UDI-DI</b>	76152082APROS001VT
<b>Document-ID</b>	OTCS11258748
<b>Document Version</b>	1.0

Legal manufacturer		
	Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan/Liechtenstein www.ivoclar.com	Phone +423 / 235 35 35, Fax +423 / 235 33 60 www.ivoclar.com Legal Form: Joint Stock Company Corporate Headquarters: 9494 Schaan Registration No.: FL-0001.001.595-7 VAT No.: 50639

EU Declaration of Conformity Information	
<b>SRN</b>	LI-MF-000000522
<b>Intended Purpose</b>	Fabrication of bases for removable dentures Fabrication of hard occlusal splints Fabrication of orthodontic appliances
<b>Category (MDCG 2019-14)</b>	MDN 1209      Non-active non-implantable dental materials
<b>EMDN Code + term</b>	Q010699      Materials for the preparation of custom-made dental devices - other
<b>MDS Code</b>	MDS 1007
<b>MDT Code</b>	MDT 2006 MDT 2011
<b>EU Risk Classification (MDR Annex VIII)</b>	Medical Device Class IIa <span style="border: 1px solid black; padding: 2px;">CE 0123</span>
<b>Conformity Assessment Procedure (MDR Annex IX)</b>	<input checked="" type="checkbox"/> Quality Management System <input type="checkbox"/> Assessment of the Technical Documentation
<b>Notified Body Address</b>	<b>TÜV SÜD Product Service GmbH</b> Ridlerstrasse 65 80339 München Deutschland
<b>EC Certificate No.</b>	G10 043306 0270 Rev. 01
<b>Valid until</b>	2026-05-04

Document Control			
Name	Place of issue	Date of issue	Signature
<b>Approver (PRRC):</b> Patrik Oehri	Schaan, LI	28.02.2024	
<b>Approver (CTO):</b> Dr. Thomas Hirt	Schaan, LI	28.02.2024	

Revision History			
Version	Date	Author	Remark
1.0	2024-02-27	R. Ritter	First MDR Version

Attachment to EU Declaration of Conformity (MDR) of  
PROBASE COLD, PROBASE COLD CLE

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
000531505	ProBase Cold Monomer 500 ml	CLASS IIA	5
000531506	ProBase Cold Monomer 1000 ml	CLASS IIA	5
000531508	ProBase Cold Polymer 500 g pink	CLASS IIA	5
000531509	ProBase Cold Polymer 500 g pink-V	CLASS IIA	5
000531510	ProBase Cold Poylmer 500 g S	CLASS IIA	5
000531511	ProBase Cold Polymer 500 g clear	CLASS IIA	5
000531512	ProBase Cold Polymer 500 g US-L	CLASS IIA	5
000531513	ProBase Cold Polymer 500 g US-P	CLASS IIA	5
000531514	ProBase Cold Polymer 2x500 g pink	CLASS IIA	5
000531515	ProBase Cold Polymer 2x500 g pink-V	CLASS IIA	5
000531517	ProBase Cold Polymer 2x500 g clear	CLASS IIA	5
000531520	ProBase Cold Polymer 5x500 g pink	CLASS IIA	5
000531521	ProBase Cold Polymer 5x500 g pink-V	CLASS IIA	5
000531522	ProBase Cold Polymer 5x500 g S	CLASS IIA	5
000531523	ProBase Cold Polymer 5x500 g clear	CLASS IIA	5
000531540	ProBase Cold Polymer 20x500 g pink	CLASS IIA	5
000531542	ProBase Cold Monomer 4x1000 ml	CLASS IIA	5
000531552	ProBase Cold Polymer 20x500 g S	CLASS IIA	5
000531747	ProBase Cold Polymer 20x500 g pink-V	CLASS IIA	5
000536285	ProBase Cold Polymer 500 g 36P-V	CLASS IIA	5
000536289	ProBase Cold Polymer 5x500 g 36P-V	CLASS IIA	5
000536293	ProBase Cold Polymer 20x500 g 36P-V	CLASS IIA	5
000536331	ProBase Cold Polymer 20x500 g US-L	CLASS IIA	5
000563542	ProBase Cold Polymer 2x500 g preference	CLASS IIA	5
000578940	ProBase Cold Polymer 20x500 g Preference	CLASS IIA	5
531492AN	ProBase Cold Standard Kit pink	CLASS IIA	5
531493AN	ProBase Cold Standard Kit pink-V	CLASS IIA	5
531495AN	ProBase Cold Standard Kit clear	CLASS IIA	5
531496AN	ProBase Cold Standard Kit US-L	CLASS IIA	5

The suffix of the article number (e.g. "AN", "EN", "AL", "WW") is only used for in-house reference and relates to the language version and/or electrical plug of the product. The suffix does not belong to the official article number.

Attachment to EU Declaration of Conformity (MDR) of  
PROBASE COLD, PROBASE COLD CLE

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
531497AN	ProBase Cold Standard Kit US-P	CLASS IIA	5
531498AN	ProBase Cold Lab Kit pink	CLASS IIA	5
531499AN	ProBase Cold Lab Kit pink-V	CLASS IIA	5
531501AN	ProBase Cold Lab Kit clear	CLASS IIA	5
531502AN	ProBase Cold Lab Kit US-L	CLASS IIA	5
531503AN	ProBase Cold Lab Kit US-P	CLASS IIA	5
536281AN	ProBase Cold Standard Kit 36P-V	CLASS IIA	5
536283AN	ProBase Cold Lab Kit 36P-V	CLASS IIA	5
563541AN	ProBase Cold Standard Kit Preference	CLASS IIA	5
578952AN	ProBase Cold Lab Kit Preference	CLASS IIA	5
578953AN	ProBase Cold Lab Kit US-D	CLASS IIA	5
629291AN	ProBase Cold Standard Kit Pink-V Implant	CLASS IIA	5
629294AN	ProBase Cold Polymer 2x500g Pink-V Impl.	CLASS IIA	5

Schaan, 14.03.2024

(this document is valid without signature)