

Formblatt

Declaration of conformity

EG – Konformitätserklärung für Medizinprodukte

EC – Declaration of Conformity for Medical Devices

Wir erklären in alleiniger Verantwortung, dass die unten aufgeführten Produkte in der gelieferten Ausführung den Anforderungen der Verordnung (EU) 2017/745 und des deutschen Medizinprodukte-Durchführungsgesetz entsprechen. Die Produkte werden mit dem CE-Kennzeichen versehen.

We declare under our sole responsibility that the products listed below as delivered are in compliance with regulation (EU) 2017/745 and the German Medical Devices Implementation Act. The products are CE marked.

Produkte / Products:		
REF	Artikel/Article	Inhalt/Content
14700	Panasil binetics Putty Fast Intro pack	1 x 380 ml, 10 dynamic mixers
14701	Panasil binetics Putty Fast Refill pack	2 x 380 ml
14772	Panasil binetics Putty Fast Refill pack	2 x 380 ml
14702	Panasil binetics Putty Soft Intro pack	1 x 380 ml, 10 dynamic mixers
14703	Panasil binetics Putty Soft Refill pack	2 x 380 ml
14773	Panasil binetics Putty Soft Refill pack	2 x 380 ml
11892	Panasil contact plus X-Light Normal pack	2 x 50 ml, 8 mixing tips
28144	Panasil contact plus X-Light Promotion pack	24 x 50 ml
13401	Panasil initial contact X-Light Normal pack	2 x 50 ml, 8 mixing tips
13405	Panasil initial contact X-Light, Superbulk	150 x 50 ml
28300	Panasil initial contact X-Light, Bonuspack	10 x 50 ml, 40 mixing tips
13411	Panasil initial contact Light Normal pack	2 x 50 ml, 8 mixing tips
13415	Panasil initial contact Light, Superbulk	150 x 50 ml
28310	Panasil initial contact Light, Bonuspack	10 x 50 ml, 40 mixing tips
13431	Panasil initial contact Regular Normal pack	2 x 50 ml, 6 mixing tips
13400	Panasil initial contact X-Light Test pack	2 x 50 ml, 6 mixing tips
13461	Panasil initial contact X-Light Fast Normal pack	2 x 50 ml, 8 mixing tips
13471	Panasil initial contact Light Fast Normal pack	2 x 50 ml, 8 mixing tips
13501	Panasil monophase Medium Normal pack	2 x 50 ml, 6 mixing tips
14709	Panasil monophase Medium Refill pack	2 x 380 ml
14776	Panasil monophase Medium Refill pack	2 x 380 ml
11101	Panasil Putty Normal pack	1 x 900 ml
11103	Panasil Putty Economy pack	4 x 900 ml
11120	Panasil Putty Soft Intro pack	1 x 400 ml
11121	Panasil Putty Soft Normal pack	1 x 900 ml
11123	Panasil Putty Soft Economy pack	4 x 900 ml
11140	Panasil Putty Fast Set Intro pack	1 x 400 ml
11141	Panasil Putty Fast Set Normal pack	1 x 900 ml
11143	Panasil Putty Fast Set Economy pack	4 x 900 ml
14704	Panasil tray Fast Heavy Intro pack	1 x 380 ml, 10 dynamic mixers

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14705	Panasil tray Fast Heavy Refill pack	2 x 380 ml
14775	Panasil tray Fast Heavy Refill pack	2 x 380 ml
14706	Panasil tray Soft Heavy Intro pack	1 x 380 ml, 10 dynamic mixers
14707	Panasil tray Soft Heavy Refill pack	2 x 380 ml
14774	Panasil tray Soft Heavy Refill pack	2 x 380 ml
13541	Panasil tray Soft Heavy Normal pack	2 x 50 ml, 6 mixing tips
13545	Panasil tray Soft Heavy, Superbulk	150 x 50 ml
13551	Panasil tray Fast Heavy Normal pack	2 x 50 ml, 6 mixing tips
13561	Panasil tray Soft Heavy Fast Normal pack	2 x 50 ml, 6 mixing tips
11781	Panasil contact two in one Light Normal pack	2 x 50 ml, 6 mixing tips
28145	Panasil contact two in one Light Promotion pack	24 x 50 ml

Zweckbestimmung / Intended Purpose:	Dentales Abformmaterial / Dental Impression material
Basis-UDI-DI / Basic UDI-DI	++E217IMPPANASILVA
Risikoklasse des Produkts / Risk class of the device (gem. Anhang VIII, Abschn.3, Verordnung (EU) 2017/745) (acc. to Annex VIII, Section 3, Regulation (EU) 2017/745)	IIa Regel / Rule 19
Name und Anschrift des Herstellers / Name and address manufacturer:	Kettenbach GmbH & Co KG Im Heerfeld 7 35713 Eschenburg / Germany
Einmalige Registrierungsnummer (SRN) des Herstellers / Single Registration Number (SRN) of manufacturer:	DE-MF-000005014
Konformitätsbewertungsverfahren / Conformity assessment procedure: (gem. Verordnung (EU) 2017/745) (acc. to Regulation (EU) 2017/745)	Annex IX
Verweise auf angewandte gemeinsame Spezifikationen (GS), für die die Konformität erklärt wird / References to any common specifications (CS) used and in relation to which conformity is declared:	N/A
Benannte Stelle / Notified Body: (außer Klasse I / except for class I)	TÜV Süd Product Service GmbH Ridlerstraße 65 80339 München Germany
Kennnummer / Identification number: (außer Klasse I / except for class I)	0123
Zertifikats-Nummer / Number of Certificate: (außer Klasse I / except for class I)	G10 033098 0050

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Diese Konformitätserklärung ist gültig bis 12.08.2030, es sei denn, es wird bereits vorher auf Grund von Änderungen eine neue Konformitätserklärung erforderlich.

This Declaration is valid until 2030-08-12, unless a new Declaration of Conformity is required previously due to changes.

Eschenburg,

20.08.2025



Dr. Jörg Amborn

Person responsible for regulatory compliance according
to §15 (EU) 2017/745