

EC-Declaration of conformity

We hereby declare for

Polishers for dental application (see attached article list)

Basic UDI-DI: ++E292dentalpolishersBA

placed on the market for the first time by EVE Ernst Vetter GmbH comply with the general safety and performance requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices.

The conformity assessment procedure according to Article 52 has been carried out and the technical documentation is kept available.

This EC Declaration of Conformity is issued under the sole responsibility of

EVE Ernst Vetter GmbH
Neureutstr. 6
75210 Keltern
Germany
SRN: DE-MF-000006302
Report Number: D13195000015

The conformity assessment procedure according to Annex IX is subject to the supervision of the notified body:

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart
CE0483

The device has been identified as a medical device of risk class IIa according to Rule 05 in Annex VIII of Regulation (EU) 2017/745.

All products of the group "Dental polishers" are considered medical devices according to Article 2, paragraph 1, first indent, as they are used for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of oral diseases associated with dental prosthesis treatment. Furthermore, there is the possibility of using polishers for preventive purposes in the context of PZR treatments.

Intended use

The Dental Polishers are intended for removing, smoothing, polishing of composites, hybrid ceramics, silicate ceramics, gold/amalgam, non-precious metal alloys, prophylaxis and enamel polishing. To minimise the surface roughness of these materials to prevent plaque accumulation, for tight marginal sealing and to correct the surface after adjustment by the dentist (registration for bite control after placing the temporary restoration).

Indication:

Polishing after placement of a composite filling
polishing to maintain the tight marginal seal gold/amalgam
polishing after correction of dentures after registration
polishing with paste for prophylaxis and gloss polishing of enamel
polishing of NEM-based dentures to increase hardness and minimize attack of oral flora

This declaration of conformity applies to all product units delivered from the release date specified below. The period of validity corresponds to the term of the approval of the notified body, unless it is replaced by a newer issue beforehand.

Validity from 2023-11-22 to 2028-11-21

Keltern, 2025-02-27


Markus Schmidtke (27. Februar 2025 10:18 GMT+1)

Markus Schmidtke
PRRC

Item List:

EVE Article No.	EVE Item	REF No.	EVE Product No.	Item	Article Group	Single-use	MD Class
D711X006	DS Enhance Flex Finisher	624090	D711	DS-DT-DCP13m	DIACOMP PLUS	No	Ila
D712X006	DS Enhance Flex Polisher	624085	D712	DS-DT-DCP13f	DIACOMP PLUS	No	Ila
S757	DS Enhance Flex Intro Kit	624095	D711	DS-DT-DCP13m	DIACOMP PLUS	No	Ila
S757	DS Enhance Flex Intro Kit	624095	D712	DS-DT-DCP13f	DIACOMP PLUS	No	Ila
S758	DS Enhance Flex Sample Kit	624080	D711	DS-DT-DCP13m	DIACOMP PLUS	No	Ila
S758	DS Enhance Flex Sample Kit	624080	D712	DS-DT-DCP13f	DIACOMP PLUS	No	Ila