

EC Declaration of Conformity for Medical Products

(according to appendix VII of the guideline on medical products 93/42/EEC)

The

company

EVE Ernst Vetter GmbH
Neureutstr.6
75210 Keltern, Germany

declares sole responsibility that conformity assessment procedures have been performed for the following products, in accordance with appendix II of the directive on medical products 93/42/EEC and that they correspond with the relevant regulations for medical products in class IIa in accordance with the appendix IX classification criteria, regulation 5.

General product description:

Dental Polisher

Product names:

According to product list appendix:

Notified body:

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart

ID number: 0483

This declaration of conformity relates to all product units that are delivered from the approval date stated below. The validity period corresponds with the period of authorisation from the notified body, if it is not previously replaced by a new version.

Validity from 2019-07-08 to 2023-10-29

Keltern, 2020-09-07



Markus Schmidtke
Regulatory Affairs

Artikelnr.	Artikelbeschreibung	GP-Katalognr.
C302	TWIST DIA for Composite – Introductory Kit, M+F, 14	1201-IP
C305	TWIST DIA for Composite – Trial Kit, M+F, 14	1204-IP
Both consisting of:		
C303	TWIST DIA for Composite – Refill, M, 14	1202-IP
C304	TWIST DIA for Composite – Refill, F, 14	1203-IP
C390	TWIST DIA for Composite – Introductory Kit, M+F, 10	1211-IP
C393	TWIST DIA for Composite – Trial Kit, M+F, 10	1214-IP
Both consisting of:		
C391	TWIST DIA for Composite – Refill, M, 10	1212-IP
C392	TWIST DIA for Composite – Refill, F, 10	1213-IP
C394	TWIST DIA for Composite – Combination Kit, M, 10+14	1221-IP
Consisting of:		
C303	TWIST DIA for Composite – Refill, M, 14	1202-IP
C391	TWIST DIA for Composite – Refill, M, 10	1212-IP
C395	TWIST DIA for Composite – Combination Kit, F, 10+14	1222-IP
Consisting of:		
C304	TWIST DIA for Composite – Refill, F, 14	1203-IP
C392	TWIST DIA for Composite – Refill, F, 10	1213-IP
S457	TWIST DIA for Zirconia – Introductory Kit, C+M+F	1301-IP
Consisting of:		
D028	TWIST DIA for Zirconia – Refill, C	1302-IP
D029	TWIST DIA for Zirconia – Refill, M	1303-IP
D030	TWIST DIA for Zirconia – Refill, F	1305-IP