

**Supplement to the Certificate  
according to 93/42/EEC, Annex II, excluding 4  
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Manufacturer	DETAX GmbH
Certificate	No. D1002700048      Date: 2021-05-05 dental products, otoplastic products
Products concerned	dental products, otoplastic products
Intended change	Change of name: OLD: Detax GmbH & Co. KG <b>NEW: Detax GmbH</b>
Review report no.	P21-02005-235267

The intended change is in compliance with the requirements of the Directive 93/42/EEC.

This supplement is valid only in conjunction with the aforementioned Certificate.

The aforementioned Certificate is valid only in conjunction with this supplement.

This supplement is valid until:	2024-05-26
Registration no.:	D1002700052
Stuttgart	2022-04-29



  
Head of Notified Body

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**DETAX GmbH & Co. KG  
Carl-Zeiss-Straße 4  
76275 Ettlingen  
Germany**

for the scope

**dental products, otoplastic products  
(see attachment)**

has introduced and applies a

**Quality System**

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system  
meets all requirements according to

**Annex II – excluding Section 4  
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2021-05-05
Valid until	2024-05-26
Registration no.	D1002700048
Report no.	P21-00672-203395
Stuttgart	2021-05-05

Head of Certification Body

