

Tekno-Medical Optik-Chirurgie GmbH  
Herrn Florian Mattes  
Sattlerstraße 11  
78532 Tuttlingen  
Deutschland

Your signs, your letter dated

Our signs, our letter dated  
OPU-ITH

Phone number  
+49 7461 919996-243

Date  
2023-05-17

### Preliminary Confirmation Letter – validity of MDD certificates

Dear Mr. Mattes,

mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany) has for the manufacturer:

Tekno-Medical Optik-Chirurgie GmbH  
Sattlerstraße 11  
78532 Tuttlingen  
Deutschland

issued the following certificate in accordance with Directive 93/42/EEC:

Certificate	Certificate registration No.	Certification	Date of issue	Expiry date
21320	D1043500072	EEC 93/42 Annex V,3	2018-07-04	2023-07-04
25346	D1043500081	EEC 93/42 Annex II, without 4	2020-12-04	2023-07-04
25223	D1043500083	EEC 93/42 Annex II, without 4	2021-05-20	2023-07-04

These certificates were valid as of 20 March 2023 and have not been withdrawn afterwards.

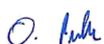
In accordance with the requirements of Art. 120 (2), second subparagraph, first sentence of Regulation (EU) 2017/745 on Medical Devices (MDR), last amended by Regulation (EU) 2023/607 the above mentioned certificates shall remain valid until the date set out in Art 120 (3a) MDR.

This confirmation requires that the manufacturer complies with the requirements laid out in Art. 120 (3c) and (3d) MDR and will undergo further surveillance according to the rules of mdc medical device certification GmbH.

According to the requirements of Art. 120 (3a) MDR, the prerequisite for placing the concerned devices on the market is fulfilled until at least 26 May 2024, unless otherwise specified by the authorities or this letter is replaced by a contrary notification by mdc.

Kind regards,

mdc medical device certification GmbH

  
i. A. Oliver Puhle  
(Project Management)