

FO	Dokumenten-Nr. – Version	Dazugehörige SOP:	Bereich	Dokument ist gültig ab	
	FO02161-01	SOP02040	QM	2016-09-06	
Titel: EC-Declaration of Conformity for Medical Devices					

EC-Declaration of Conformity for Medical Devices

according to MDD 93/42/EEC (2007/47/EC)

Manufacturer: MORCHER® GmbH
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Product name: **EYEJET® CTR (Injector including Capsular Tension Rings)**

Classification: IIb (according to MDD 93/42/EEC Annex IX, Rule 8)

Start of CE-marking: 28.10.2007

We declare under sole responsibility that **Eyejet® CTR** (different variants are listed in the attached table) are in conformity with Medical Device Directive 93/42/EEC and its Annex I and Annex II excluding (4).
 MORCHER® products have been CE marked, as laid down in Article 17 and Annex XII of the MDD 93/42/EEC.

Applied standards with exclusion of inapplicable parts of the standards:

DIN EN ISO 11979 - 1: 2019-05
 DIN EN ISO 11979 - 3: 2013-04 (without 4.3, 4.5, 4.6, 4.7, and 6)
 DIN EN ISO 11979 - 4: 2013-01 (without 5, No. 10, 12, and 15)
 DIN EN ISO 11979 - 5: 2010-11 (without 5.5 and 5.6)
 DIN EN ISO 11979 - 6: 2015-02 (without 4.3.2.1 Point b, c, f and I)
 DIN EN ISO 11979 - 8: 2017-08 (without 9.1)

Name, address and identification number of the Notified Body:

TÜV SÜD Product Service GmbH
 Ridlerstr. 65
 80339 Munich, GERMANY
 Identification No. 0123

This declaration is valid from the day of release to **2024-05-26**

Place, Date: Stuttgart, 2020-01-24

Sign: _____


 Eric Morcher, Head of QM

MORCHER® GmbH

List of CE marked products

Product Category: Capsular Rings preloaded in an Injector for Eye Implants (EYEJET)
Technical File: EYEJET CTR
Classification acc. to 93/42/EEC Annex IX:
Rule 8, classification: IIb

<i>Type</i>	<i>No.</i>	<i>Description</i>
10C	10C RIGHT	CR, tension ring, PC
10G	10G RIGHT	CR, tension ring, PC
10L	10L RIGHT	CR, tension ring, PC
13	13 RIGHT	CR, tension ring, PC
13A	13A RIGHT	CR, tension ring, PC
13B	13B RIGHT	CR, tension ring, PC
14	14 LEFT	CR, tension ring, PC
14	14 RIGHT	CR, tension ring, PC
1431	1431 RIGHT	CR, tension ring, PC
14A	14A LEFT	CR, tension ring, PC
14A	14A RIGHT	CR, tension ring, PC
14C	14C LEFT	CR, tension ring, PC
14C	14C RIGHT	CR, tension ring, PC
15	15 RIGHT	CR, tension ring, PC
15A	15A RIGHT	CR, tension ring, PC
15B	15B RIGHT	CR, tension ring, PC
19D	19D	CR, tension ring, PC