

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: - **CR (Capsular Rings)**
- **EYEJET® CTR (Injector including Capsular Rings)**

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

Start of CE-marking: 11.10.1997

We declare under sole responsibility that **Capsular Rings and 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:

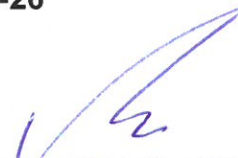
- DIN EN ISO 11979 - 1: 2019-05
- DIN EN ISO 11979 - 3: 2013-04 (without 4.3, 4.5, 4.6, 4.7, and 6)
- DIN EN ISO 11979 - 4: 2013-01 (without 5, No. 10, 12, and 15)
- DIN EN ISO 11979 - 5: 2010-11 (without 5.5 and 5.6)
- DIN EN ISO 11979 - 6: 2015-02 (without 4.3.2.1 Point b, c, f and l, and 4.3.2.2)
- DIN EN ISO 11979 - 8: 2017-08 (without 9.1)

Name, address and identification number of the Notified Body:

mdc medical device certification GmbH
Kriegerstraße 6
70191 Stuttgart
Germany
Identification No. 0483

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

Place, Date: Stuttgart, 2021-05-25

Sign: 
Markus Lang, Head of QM

MORCHER® GmbH
List of CE marked products

<i>Product Category: Capsular Rings</i>
<i>Technical File: Capsular Rings</i>
<i>Classification acc. to 93/42/EEC Annex IX</i>
<i>Rule 8, classification: IIb</i>

<i>Type</i>	<i>No.</i>	<i>Description</i>
10C	10C NO	CR, tension ring, PC
13	13	CR, tension ring, PC
13A	13A	CR, tension ring, PC
13B	13B	CR, tension ring, PC
13S	13S	CR, tension ring, PC
14	14	CR, tension ring, PC
14A	14A	CR, tension ring, PC
14C	14C	CR, tension ring, PC
1G	1G	CR, Cionni ring, PC
1L	1L	CR, Cionni ring, PC
1S	1S	CR, Cionni ring, PC
20C	20C NO	CR, tension ring, PC
2C	2C	CR, Cionni ring, PC
2L	2L	CR, Cionni ring, PC
2S	2S	CR, Cionni ring, PC
6D	6D	CR, segment ring, PC
6E	6E	CR, segment ring, PC
6F	6F	CR, segment ring, PC
9L	9L	CR, segment ring, PC
10	ACTR10	CR, tension ring, PC
11	ACTR11	CR, tension ring, PC
12	ACTR12	CR, tension ring, PC



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 LEFT	CR, tension ring, PC
15	15 RIGHT	CR, tension ring, PC
15A	15A LEFT	CR, tension ring, PC
15A	15A RIGHT	CR, tension ring, PC
15B	15B LEFT	CR, tension ring, PC
15B	15B RIGHT	CR, tension ring, PC
19D	19D	CR, tension ring, PC
20C	20C RIGHT	CR, tension ring, PC