

**Konformitätserklärung  
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG  
Carl-Braun-Straße 1  
34212 Melsungen  
Deutschland/Germany**erklären in eigener Verantwortung,  
dass das/die Produkt/e**Askina® Ocula**  
Augenkompressen, steril

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie  
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni  
1993 über Medizinprodukte,  
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**  
nach Anhang V und VII  
der oben genannten Richtlinie**Klassifizierung**  
gemäß Anhang IX der oben genannten  
Richtlinie:  
Klasse I steril**Benannte Stelle**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Deutschland  
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**  
1997-08**Gültig bis**  
2024-05-26hereby declare in our own responsibility  
that the product/s**Askina® Ocula**  
Compresses for eyes, sterile

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14 June 1993  
concerning Medical Devices,  
amended by Directive 2007/47/EG**Conformity assessment procedure**  
according to annex V and VII  
of the Directive named above**Classification**  
according to annex IX of the Directive named  
above:  
Class I sterile**Notified body**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Germany  
Identification number 0123**Date of first CE-marking**  
1997-08**Valid until**  
2024-05-26

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product Name</b>	<b>Klasse / Class</b>
9015116	Askina® Ocula	I steril / I sterile
9015124	Askina® Ocula	I steril / I sterile

**Amendment Information**

<b>Version</b>	<b>Description of the changes</b>
12	Annual revision acc. to TÜV audit 2009
13	Annual revision acc. to TÜV audit 2009
14	Annual revision acc. to TÜV audit 05-2009 Version 1: BBMAG OPM; Version 2: BBMAG
15	Adaption to SOP HO-DDDD-M-5-2-05-715
16	Adaptation of validity to the MDR-deadline

Title: Declaration of Conformity - 067-001(04) - Askina Ocula steril Initiator: Anna Heil

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Heil, Anna (heilaade)  
Title: Administrator Regulatory Affairs  
Date: Friday, 03 April 2020, 15:04 W. Europe Daylight Time  
Meaning: Document signed as Author

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UserName: Moeller, Thomas (moelthde)  
Title: HC-QM-DE08A - Vice President QM Systems & Quality Compliance  
Date: Monday, 06 April 2020, 08:07 W. Europe Daylight Time  
Meaning: Approve Document

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UserName: Gaudin, Hans-Ulrich (gaudhade)  
Title: OM-RADE08S Head of Regulatory Affairs OPM DE  
Date: Tuesday, 07 April 2020, 19:06 W. Europe Daylight Time  
Meaning: Approve Document

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