

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® Mullkompressen
Komresse, Mull, steril

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni
1993 über Medizinprodukte,
geändert durch Richtlinie 2007/47/EG

Konformitätsbewertungsverfahren
nach Anhang II
ohne Abschnitt 4
der oben genannten Richtlinie

Klassifizierung
gemäß Anhang IX der oben genannten
Richtlinie:
Klasse IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123

Datum der ersten CE-Kennzeichnung
1998-01

Gültig bis
2024-05-26

hereby declare in our own responsibility
that the product/s

Askina® Mullkompressen
Compresses., gauze, 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 II
without part 4
of the Directive named above

Classification
according to annex IX of the Directive named
above:
Class IIa

Notified body
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123

Date of first CE-marking
1998-01

Valid until
2024-05-26

Anlage I / Attachment I

| Art.-Nr. / Art. No. | Produktname / Product Name | Klasse / Class |
|----------------------------|-----------------------------------|-----------------------|
| 9031103N | Askina® Mullkompressen | Ila |
| 9031111N | Askina® Mullkompressen | Ila |
| 9031120N | Askina® Mullkompressen | Ila |
| 9031138N | Askina® Mullkompressen | Ila |
| 9031200N | Askina® Mullkompressen | Ila |
| 9031219N | Askina® Mullkompressen | Ila |
| 9031227N | Askina® Mullkompressen | Ila |
| 9031235N | Askina® Mullkompressen | Ila |

Amendment information

| Version | Description of the changes |
|---------|---|
| 01 | Restructuring of Technical Documentation 067-015 -> 067-001(15) |
| 02 | Delete Out of Market art. no. 9031219 |
| 03 | Delete Out of Market art. no. 4002, 4062, 9031120, 9031227 |
| 04 | Delete Out of Market art. no. 9031200 |
| | |

Title: Declaration of Conformity - 067-001(15) - Askina Mullkompressen sterile 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: Junior Manager Regulatory Affairs
Date: Friday, 13 November 2020, 14:01 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Moeller, Thomas (moelthde)
Title: HC-QM-DE08A - Vice President QM Systems & Quality Compliance
Date: Monday, 16 November 2020, 08:06 W. Europe Daylight Time
Meaning: Approve Document

UserName: Gaudin, Hans-Ulrich (gaudhade)
Title: OM-RADE08S Head of Regulatory Affairs OPM DE
Date: Monday, 16 November 2020, 09:24 W. Europe Daylight Time
Meaning: Approve Document
