

Konformitätserklärung Declaration of Conformity

Wir

We

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201

erklären in eigener Verantwortung,
dass die Produkte

hereby declare in our own responsibility
that the products

Exadoral®

Exadoral®

5 ml Syringe ALDO Union Oral Dispenser
3 ml Apirofeno Oral Dispenser FOR
ORAL USE

5 ml Syringe ALDO Union Oral Dispenser
3 ml Apirofeno Oral Dispenser FOR
ORAL USE

5 ml Oral Dispenser Dosificador Oral –
NORMON FOR ORAL USE NON-STERILE

5 ml Oral Dispenser Dosificador Oral –
NORMON FOR ORAL USE NON-STERILE

5 ml Dispensador Oral (6 mg/3 mL) FOR
ORAL USE NON-STERILE

5 ml Dispensador Oral (6 mg/3 mL) FOR
ORAL USE NON-STERILE

5 ml Farmalider Oral Dispenser FOR
ORAL USE

5 ml Farmalider Oral Dispenser FOR
ORAL USE

5 ml Farmalider, IBUPROM FOR ORAL
USE

5 ml Farmalider, IBUPROM FOR ORAL
USE

2 mL Oral Dispenser Dosificador Oral –
NORMON FOR ORAL USE NON-STERILE

2 mL Oral Dispenser Dosificador Oral –
NORMON FOR ORAL USE NON-STERILE

5ml APAP® Oral Dispenser FOR ORAL
USE

5ml APAP® Oral Dispenser FOR ORAL
USE

5 mL Oral Dispenser Dosificador Oral –
NORMON FOR ORAL USE NON-STERILE

5 mL Oral Dispenser Dosificador Oral –
NORMON FOR ORAL USE NON-STERILE

5 ml Apiretal Oral Dispenser FOR ORAL
USE

5 ml Apiretal Oral Dispenser FOR ORAL
USE

5 ml Apirofeno Oral Dispenser FOR
ORAL USE

5 ml Apirofeno Oral Dispenser FOR
ORAL USE

10 ml Oral Dispenser Dosificador Oral –
NORMON FOR ORAL USE NON-STERILE

10 ml Oral Dispenser Dosificador Oral –
NORMON FOR ORAL USE NON-STERILE

1 mL Dispenser Lacovin®

1 mL Dispenser Lacovin®

2-piece Oral Dispenser non-sterile multiple use
Basis UDI-DI: 4039239000002872F
(Artikelnummern siehe Anlage I)

2-piece Oral Dispenser non-sterile multiple use
Basis UDI-DI: 4039239000002872F
(article numbers see attachment I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745 übereinstimmen

Konformitätsbewertungsverfahren
nach Anhang IX der oben genannten
Verordnung

Klassifizierung
gemäß Anhang VIII der oben genannten
Verordnung
Klasse I Messfunktion

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis
gemäß gültigem EU Zertifikat
(Nr. G11 012974 0626)

are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745

Conformity Assessment Procedure
according to annex IX of the Regulation named
above

Classification
according to annex VIII of the Regulation named
above
Class I measuring function

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Valid until
according to our valid EU Certificate
(No. G11 012974 0626)

Anlage I / Attachment I

Basic UDI-DI: 4039239000002872F

Art.-Nr. / Produktname / Product name

Art. No.

4606970 Exadoral®

4606975 Exadoral®

4608680 Exadoral®

4606065 5 ml Syringe ALDO Union Oral Dispenser

4606925 3 ml Apirofeno Oral Dispenser FOR ORAL USE

4606940 5 ml Oral Dispenser Dosificador Oral – NORMON
FOR ORAL USE NON-STERILE

4606945 5 ml Dispensador Oral (6 mg/3 mL) FOR ORAL
USE NON-STERILE

4606950 5 ml Farmalider Oral Dispenser FOR ORAL USE

4606951 5 ml Farmalider, IBUPROM FOR ORAL USE

4606952 2 mL Oral Dispenser Dosificador Oral – NORMON
FOR ORAL USE NON-STERILE

4606954 5ml APAP® Oral Dispenser FOR ORAL USE

4606972 5 mL Oral Dispenser Dosificador Oral – NORMON
FOR ORAL USE NON-STERILE

4606980 5 ml Apiretal Oral Dispenser FOR ORAL USE

4606985 5 ml Apirofeno Oral Dispenser FOR ORAL USE

4607040 10 ml Oral Dispenser Dosificador Oral – NORMON
FOR ORAL USE NON-STERILE

4608961 1 mL Dispenser Lacovin®

Klasse / Class

I Messfunktion / I measuring function

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I Messfunktion / I measuring function

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Document amendment information

Version	Description of the changes
2.0	Addition of article nos. 4606065, 4606925, 4606940, 4606945, 4606950, 4606951, 4606952, 4606954, 4606972, 4606980, 4606985, 4607040, and 4608961 based on MDR conversion project S.101-0474.01 (change control HC-CHC-M-DIV-2188). Replacement of the German translation of the intended purpose for the official English version of the intended purpose of the Basic UDI-DI and formal adaptations according to the template. Inclusion of the product group name to the document name.
1.0	First Issue under Medical Device Regulation (MDR) 2017/745

Title: Declaration of Conformity - 092-101 - MDR - Oral Dispenser (non-sterile, multiple use) Initiator: Jascha T Manschwetus

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

UserName: Manschwetus, Jascha (mansjsde)
Title: Junior Manager Regulatory Affairs | CoE Infusion & Pain Therapy
Date: Friday, 17 May 2024, 17:15 W. Europe Daylight Time
Meaning: Document signed as Author

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UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Friday, 17 May 2024, 17:53 W. Europe Daylight Time
Meaning: Approve Document

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UserName: Brand, Thomas (brantode)
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Date: Friday, 17 May 2024, 20:45 W. Europe Daylight Time
Meaning: Approve Document

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