

**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**Exadoral®,
Exadoral™,
Oral Dispenser**Sets zur oralen Applikation von Arzneimitteln
(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 VII und V
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse I steril Messfunktion
Klasse I Messfunktion**Benannte Stelle**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**
1998-10**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Exadoral®,
Exadoral™,
Oral Dispenser**Sets for oral use of drugs
(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June
1993
concerning Medical Devices
amended by Directive 2007/47/EC**Conformity Assessment Procedure**
according to annex VII and V
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class I sterile measuring function
Class I measuring function**Notified Body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Date of first CE-marking**
1998-10**Valid until**
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4604961-02	Exadoral™	I Messfunktion / I measuring function
4606065	5 ml Syringe ALDO Union Oral Dispenser	I Messfunktion / I measuring function
4606917-02	Exadoral™	I Messfunktion / I measuring function
4606925	3 ml Apirofeno Oral Dispenser FOR ORAL USE	I Messfunktion / I measuring function
4606927-02	Exadoral™	I Messfunktion / I measuring function
4606940	5 ml Oral Dispenser Dosificador Oral – NORMON FOR ORAL USE NON- STERILE	I Messfunktion / I measuring function
4606945	5 ml Dispensador Oral (6 mg/3 mL) FOR ORAL USE NON-STERILE	I Messfunktion / I measuring function
4606947-02	Exadoral™	I Messfunktion / I measuring function
4606950	5 ml Farmalider Oral Dispenser FOR ORAL USE	I Messfunktion / I measuring function
4606951	5 ml Farmalider, IBUPROM FOR ORAL USE	I Messfunktion / I measuring function
4606952	2 mL Oral Dispenser Dosificador Oral – NORMON FOR ORAL USE NON-STERILE	I Messfunktion / I measuring function
4606954	5ml APAP® Oral Dispenser FOR ORAL USE	I Messfunktion / I measuring function
4606960	Exadoral®	I steril Messfunktion / I sterile measuring function
4606962	Exadoral®	I steril Messfunktion / I sterile measuring function
4606963	Exadoral®	I steril Messfunktion / I sterile measuring function
4606967	Exadoral®	I steril Messfunktion / I sterile measuring function
4606970	Exadoral®	I Messfunktion / I measuring function
4606970-02	Exadoral™	I Messfunktion / I measuring function
4606972	5 mL Oral Dispenser Dosificador Oral – NORMON FOR ORAL USE NON-STERILE	I Messfunktion / I measuring function
4606973	10 ml Oral Dispenser	I Messfunktion / I measuring function
4606975	Exadoral®	I Messfunktion / I measuring function
4606975-02	Exadoral™	I Messfunktion / I measuring function
4606977-02	Exadoral™	I Messfunktion / I measuring function

4606980	5 ml Apiretal Oral Dispenser FOR ORAL USE	I Messfunktion / I measuring function
4606985	5 ml Apirofeno Oral Dispenser FOR ORAL USE	I Messfunktion / I measuring function
4606988	10 ml Apirofeno Oral Dispenser FOR ORAL USE	I Messfunktion / I measuring function
4606990	2 ml Exadoral® Oral Dispenser FOR ORAL USE	I Messfunktion / I measuring function
4606990-02	Exadoral™	I Messfunktion / I measuring function
4606995	20 ml Exadoral® Oral Dispenser FOR ORAL USE	I Messfunktion / I measuring function
4606995-02	Exadoral™	I Messfunktion / I measuring function
4607040	10 ml Oral Dispenser Dosificador Oral – NORMON FOR ORAL USE NON-STERILE	I Messfunktion / I measuring function
4607961	Exadoral®	I steril Messfunktion / I sterile measuring function
4608069	Seringue Orale	I Messfunktion / I measuring function
4608660	Exadoral®	I steril Messfunktion / I sterile measuring function
4608661	Exadoral®	I steril Messfunktion / I sterile measuring function
4608662	Exadoral®	I steril Messfunktion / I sterile measuring function
4608663	Exadoral®	I steril Messfunktion / I sterile measuring function
4608667	Exadoral®	I steril Messfunktion / I sterile measuring function
4608680	Exadoral®	I Messfunktion / I measuring function
4608961	1 mL Dispenser Lacovin®	I Messfunktion / I measuring function
4609660	Exadoral®	I steril Messfunktion / I sterile measuring function
4609662	Exadoral®	I steril Messfunktion / I sterile measuring function
4609663	Exadoral®	I steril Messfunktion / I sterile measuring function
4609667	Exadoral®	I steril Messfunktion / I sterile measuring function

Amendment Information

Version	Description of changes
07.0	Add art. no. 4607040
08.0	Add art. no. 4608680
09.0	Update validity
10.0	Delete art. no. 4600250C, 4600255C, 4600260C, 4600265C will be covered by DoC 39.05.223
11.0	Add art. no. 4606972, 4606952

Title: Declaration of Conformity - 092-100 - Exadoral Initiator: Caroline ? Herbst

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

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