

Wir

We

B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germanyerklären in eigener Verantwortung,
dass das/die Produkt/e**Diacan®**
Diacan® S
Diacan® Set
Singucan® Single Needle**A.V. Fistula Needles**
(article numbers see attachment I)mit den Anforderungen der folgenden Richtlinien
übereinstimmt/übereinstimmen:Richtlinie 93/42/EWG des Rates vom
14. Juni 1993 über Medizinprodukte**Konformitätsbewertungsverfahren:**
nach Anhang II Absatz 3
der Richtlinie 93/42/EWG**Klassifizierung**
gemäß Anhang IX der oben Richtlinie 93/42/EWG:
Klasse IIa, Regel 7**EG-Zertifikat Nr.**
G1 066097 0096 Rev. 02**Benannte Stelle:**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung:**
1998-03Doc #: 68/04-RA-sz
Doc Rev #: 20.0
Rev date: 2020-11-20Gültigkeit dieser Erklärung:
von 2020-11-25
bis 2024-05-26hereby declare in our own responsibility
that the product/s**Diacan®**
Diacan® S
Diacan® Set
Singucan® Single Needle**A.V. Fistula Needles**
(article numbers see attachment I)

is/are in compliance with the following directives:

Council Directive 93/42/EEC of 14 June 1993
on medical devices**Conformity assessment procedure:**
according to annex II clause 3
of Council Directive 93/42/EEC**Classification**
according to annex IX of Council Directive 93/42/EEC:
Class IIa, Rule 7**EC Certificate No.**
G1 066097 0096 Rev. 02**Notified body:**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany
Identification number 0123**Date of first CE-marking:**
1998-03Doc #: 68/04-RA-sz
Doc Rev #: 20.0
Rev date: 2020-11-20Validity of this declaration:
from 2020-11-25
until 2024-05-26

Radeberg, 2020-11-23


Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

Mirandola, 2020-11-20


Dr. Giuliana Gavioli
Head of Division RA

Anlage I / Attachment I

Art. No.	Description	Type (A/V)	Needle Size (G)	Needle Length (mm)	Tubing Length (mm)	Sterilization Type
7023253	Diacan®	A	15	20	150	gamma
7023353	Diacan®	V	15	20	150	gamma
7023254	Diacan®	A	15	20	300	gamma
7023354	Diacan®	V	15	20	300	gamma
7023255	Diacan®	A	15	25	150	gamma
7023355	Diacan®	V	15	25	150	gamma
7023256	Diacan®	A	15	25	300	gamma
7023356	Diacan®	V	15	25	300	gamma
70232560	Diacan®	A	15	25	300	gamma
70233560	Diacan®	V	15	25	300	gamma
7023261	Diacan®	A	16	15	150	gamma
7023263	Diacan®	A	16	20	150	gamma
7023363	Diacan®	V	16	20	150	gamma
7023264	Diacan®	A	16	20	300	gamma
7023364	Diacan®	V	16	20	300	gamma
7023265	Diacan®	A	16	25	150	gamma
7023365	Diacan®	V	16	25	150	gamma
7023266	Diacan®	A	16	25	300	gamma
7023366	Diacan®	V	16	25	300	gamma
7026420N	Diacan®	A	16	25	300	EtO
7026528N	Diacan®	V	16	25	300	EtO
7026617N	Diacan®	A	17	25	300	EtO
7026714N	Diacan®	V	17	25	300	EtO
70232660	Diacan®	A	16	25	300	gamma
70233660	Diacan®	V	16	25	300	gamma
7023273	Diacan®	A	17	20	150	gamma
7023373	Diacan®	V	17	20	150	gamma
7023274	Diacan®	A	17	20	300	gamma
7023374	Diacan®	V	17	20	300	gamma
7023275	Diacan®	A	17	25	150	gamma
7023375	Diacan®	V	17	25	150	gamma
7023276	Diacan®	A	17	25	300	gamma
7023376	Diacan®	V	17	25	300	gamma
70232760	Diacan®	A	17	25	300	gamma

Radeberg, 2020-11-23

Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

Mirandola, 2020-11-20

Dr. Giuliana Gavioli
Head of Division RA

Art. No.	Description	Type (A/V)	Needle Size (G)	Needle Length (mm)	Tubing Length (mm)	Sterilization Type
70233760	Diacan®	V	17	25	300	gamma
7023453	Diacan® S	A	15	20	150	gamma
7023553	Diacan® S	V	15	20	150	gamma
7023454	Diacan® S	A	15	20	300	gamma
7023554	Diacan® S	V	15	20	300	gamma
7023455	Diacan® S	A	15	25	150	gamma
7023555	Diacan® S	V	15	25	150	gamma
7023456	Diacan® S	A	15	25	300	gamma
7023556	Diacan® S	V	15	25	300	gamma
7023461	Diacan® S	A	16	15	150	gamma
7023561	Diacan® S	V	16	15	150	gamma
7023562	Diacan® S	V	16	15	300	gamma
7023463	Diacan® S	A	16	20	150	gamma
7023563	Diacan® S	V	16	20	150	gamma
7023464	Diacan® S	A	16	20	300	gamma
7023564	Diacan® S	V	16	20	300	gamma
7023465	Diacan® S	A	16	25	150	gamma
7023565	Diacan® S	V	16	25	150	gamma
7023466	Diacan® S	A	16	25	300	gamma
7023566	Diacan® S	V	16	25	300	gamma
70234660	Diacan® S	A	16	25	300	gamma
70235660	Diacan® S	V	16	25	300	gamma
7023572	Diacan® S	V	17	15	300	gamma
7023473	Diacan® S	A	17	20	150	gamma
7023573	Diacan® S	V	17	20	150	gamma
7023474	Diacan® S	A	17	20	300	gamma
7023574	Diacan® S	V	17	20	300	gamma
7023475	Diacan® S	A	17	25	150	gamma
7023575	Diacan® S	V	17	25	150	gamma
7023476	Diacan® S	A	17	25	300	gamma
7023576	Diacan® S	V	17	25	300	gamma
7023643	Diacan® Set	A/V	14	20	150	gamma
7023653	Diacan® Set	A/V	15	20	150	gamma
7023654	Diacan® Set	A/V	15	20	300	gamma
7023655	Diacan® Set	A/V	15	25	150	gamma
7023656	Diacan® Set	A/V	15	25	300	gamma
7023661	Diacan® Set	A/V	16	15	150	gamma
7023663	Diacan® Set	A/V	16	20	150	gamma
7023664	Diacan® Set	A/V	16	20	300	gamma

Radeberg, 2020-11-23

Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

Mirandola,

2020-11-20

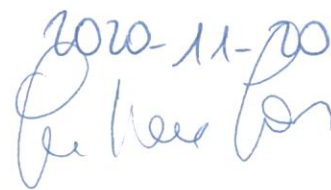
Dr. Giuliana Gavioli
Head of Division RA

Art. No.	Description	Type (A/V)	Needle Size (G)	Needle Length (mm)	Tubing Length (mm)	Sterilization Type
7023665	Diacan® Set	A/V	16	25	150	gamma
7023666	Diacan® Set	A/V	16	25	300	gamma
7023671	Diacan® Set	A/V	17	15	150	gamma
7023673	Diacan® Set	A/V	17	20	150	gamma
7023674	Diacan® Set	A/V	17	20	300	gamma
7023675	Diacan® Set	A/V	17	25	150	gamma
7023684	Diacan® Set	A/V	18	20	300	gamma
7023753	Singucan® Single Needle	A/V	15	20	150	gamma
7023755	Singucan® Single Needle	A/V	15	25	150	gamma
7023763	Singucan® Single Needle	A/V	16	20	150	gamma
7023765	Singucan® Single Needle	A/V	16	25	150	gamma
7023773	Singucan® Single Needle	A/V	17	20	150	gamma
7023005N	Diacan®	A	15	25	300	EtO
7023019N	Diacan®	V	15	25	300	EtO
7023004N	Diacan®	A	16	25	300	EtO
7023018N	Diacan®	V	16	25	300	EtO
7023003N	Diacan®	A	17	25	300	EtO
7023017N	Diacan®	V	17	25	300	EtO

Radeberg, 2020-11-23

Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

Mirandola, 2020-11-20

Dr. Giuliana Gavioli
Head of Division RA