

La sottoscritta

We

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11
41037 Mirandola (MO)
Italy

SRN (Single Registration No.) IT-MF-000010730

Dichiara sotto la propria responsabilità
che il/i prodotto/ihereby declare in our own responsibility
that the product/s

Basis-UDI-DI 40392390000009973M

Basic-UDI-DI 40392390000009973M

Diveen®

(Codici Articolo vedi Allegato I)

Diveen®

(article numbers see attachment I)

è/sono in conformità ai requisiti del Regolamento sui
Dispositivi Medici (UE) 2017/745is/are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745**Procedura di conformità:**
In accordo all'allegato IX
del Regolamento sopra citato**Conformity Assessment Procedure**
according to annex IX
of the Regulation named above**Classificazione**In accordo all'Allegato VIII del Regolamento sopra
citato
Classe IIa, Regola 5**Classification**according to annex VIII of the Regulation named above
Class IIa, Rule 5**Certificato CE Nr.**

G10 019717 0034 Rev. 01

EC Certificate No.

G10 019717 0034 Rev. 01

Ente Notificato:TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Monaco, Germania
Nr. di identificazione 0123**Notified Body**TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Germany
Identification number 0123**Data prima marcatura CE:**

2024-11

Date of first CE-marking:

2024-11

Doc #: 26/24-RA-mp

Doc Rev #: 1.0

Rev date: 2024-11-13


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Doc Rev #: 1.0

Rev date: 2024-11-13

Validità della dichiarazione:dal 2024-11-22
fino al 2025-11-15**Validity of this declaration:**from 2024-11-22
until 2025-11-15

Mirandola, 2024-11-14


Dr. Alexander Ehm
Head of CoE IPC, Renal & WOC Consumables

Mirandola, 2024-11-14


Chiara Bergamini
Vice President Regulatory Affairs

Allegato I / Attachment I

Nr. Art. / Art. No.	Descrizione Articolo / Article description	Classe / Class	Regola / Rule
3022	Diveen® Small size / Box of 15	Ila	5
3023	Diveen® Medium size / Box of 15	Ila	5
3025	Diveen® Set Box of 1 small + 1 medium + 1 applicator	Ila	5
3132	Diveen® Small size / Box of 5	Ila	5
3133	Diveen® Medium size / Box of 5	Ila	5

Mirandola, 2024-11-14

Dr. Alexander Ehm
Head of CoE IPC, Renal & WOC Consumables

Mirandola, 2024-11-14

Chiara Bergamini
Vice President Regulatory Affairs

Effective

Doc #: 26/24-RA-mp – Rev. 1.0