



MDR Dichiarazione di Conformità
MDR Declaration of Conformity
(Form)

B. Braun Avitum
IMS Avitum PBU – Mirandola
Form-ID: SOP-MBC853
Version: 1.0
Page: 1 of 5

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/i

Basic-UDI-DI: 40392390000001792B

Actreen®

(Codici Articolo vedi Allegato I)

è/sono in conformità ai requisiti del Regolamento sui
Dispositivi Medici (UE) 2017/745

Procedura di conformità:
In accordo all'allegato IX Capitoli I e III
del Regolamento sopra citato

Classificazione
In accordo all'Allegato VIII del Regolamento sopra
citato
Classe I, Regola 5

Certificato CE Nr.
G11 019717 00 35 Rev.02

Ente Notificato:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Monaco, Germania
Nr. di identificazione 0123

Data prima marcatura CE:
2024-07

Doc #: 112/24-RA-mp
Doc Rev #: 1.0
Rev date: 2024-07-08

Validità della dichiarazione:
dal 2024-07-08
fino al 2025-11-15

hereby declare in our own responsibility
that the product/s

Basic-UDI-DI: 40392390000001792B

Actreen®

(article numbers see attachment I)

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

Conformity Assessment Procedure
according to annex IX Chapters I and III
of the Regulation named above

Classification
according to annex VIII of the Regulation named above

Class I, Rule 5

EC Certificate No.
G11 019717 00 35 Rev.02

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

Date of first CE-marking:
2024-07

Doc #: 112/24-RA-mp
Doc Rev #: 1.0
Rev date: 2024-07-08

Validity of this declaration:
from 2024-07-08
until 2025-11-15

Mirandola,

2024-07-08

Dr. Alexander Ehm
Head of CoE Renal & WOC Consumables

Mirandola,

2024-07-08

Chiara Bergamini
Vice President Regulatory Affairs



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Allegato I / Attachment I

Nr. Art. / Art. No.	Descrizione Articolo / Article description	Tipo/ Type	Classe / Class	Regola / Rule
226108	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226110	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226112	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226114	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226116	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226208	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226210	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226212	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226214	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226216	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226218	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226306	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226308	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226310	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226312	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226314	Actreen® Glyc Set	Box of 30	class Is	Rule 5
226316	Actreen® Glyc Set	Box of 30	class Is	Rule 5
238108	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238110	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238112	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238114	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238116	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238118	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238208	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238210	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238212	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5

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238214	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238216	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238218	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238306	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238308	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238310	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238312	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238314	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
238316	Actreen® Hi-Lite Cath	Box of 30	class Is	Rule 5
242110	Actreen® Hi-Lite Set	Box of 30	class Is	Rule 5
242112	Actreen® Hi-Lite Set	Box of 30	class Is	Rule 5
242114	Actreen® Hi-Lite Set	Box of 30	class Is	Rule 5
242116	Actreen® Hi-Lite Set	Box of 30	class Is	Rule 5
242118	Actreen® Hi-Lite Set	Box of 30	class Is	Rule 5
242210	Actreen® Hi-Lite Set	Box of 30	class Is	Rule 5
242212	Actreen® Hi-Lite Set	Box of 30	class Is	Rule 5
242214	Actreen® Hi-Lite Set	Box of 30	class Is	Rule 5
242216	Actreen® Hi-Lite Set	Box of 30	class Is	Rule 5
242218	Actreen® Hi-Lite Set	Box of 30	class Is	Rule 5
228108	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228110	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228112	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228114	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228116	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228118	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228208	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228210	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228212	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228214	Actreen® Lite Cath	Box of 30	class Is	Rule 5

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228216	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228218	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228306	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228308	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228310	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228312	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228314	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228316	Actreen® Lite Cath	Box of 30	class Is	Rule 5
228108D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228110D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228112D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228114D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228116D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228118D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228208D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228210D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228212D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228214D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228216D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228218D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228306D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228308D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228310D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228312D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228314D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228316D	Actreen® Lite Cath	Box of 60	class Is	Rule 5
228008	Actreen® Mini Cath	Box of 30	class Is	Rule 5
228010	Actreen® Mini Cath	Box of 30	class Is	Rule 5
228012	Actreen® Mini Cath	Box of 30	class Is	Rule 5

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228014	Actreen® Mini Cath	Box of 30	class Is	Rule 5
228016	Actreen® Mini Cath	Box of 30	class Is	Rule 5
2280126D	Actreen® Mini Cath	Box of 60	class Is	Rule 5
2280106D	Actreen® Mini Cath	Box of 60	class Is	Rule 5
239010	Actreen® Mini Set	Box of 30	class Is	Rule 5
239012	Actreen® Mini Set	Box of 30	class Is	Rule 5
239014	Actreen® Mini Set	Box of 30	class Is	Rule 5

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