

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/sUDI-DI di Base: **4039239000001792B**Basic-UDI-DI: **4039239000001792B****Actreen®**L'uso previsto (scopo) di Actreen® è quello di fornire il
cateterismo urinario intermittente della vescica,
introducendo il catetere attraverso l'uretra per drenare
l'urina dalla vescica.
(Codici Articolo vedi Allegato I)**Actreen®**The intended use (purpose) of Actreen® is to provide
intermittent urinary catheterization of the bladder, by
introducing the catheter through the urethra to drain the
urine from the bladder.
(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 a allegato IX Capitolo I e III
del Regolamento sopra citato**Conformity Assessment Procedure**according to annex IX Chapter I and III
of the Regulation named above**Classificazione**In accordo all'Allegato VIII del Regolamento sopra citato
Classe I sterile, Regola 5**Classification**according to annex VIII of the Regulation named above
Class I sterile, Rule 5**Certificato UE Sistema di gestione Qualità Nr.**
G15 019717 0043 Rev. 00**EU Quality Management System Certificate No.**
G15 019717 0043 Rev. 00**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:**
2024-07**Date of first CE-marking:**
2024-07Doc #: 112/24-RA-mp
Doc Rev #: 5.0
Rev date: 2026-04-17Doc #: 112/24-RA-mp
Doc Rev #: 5.0
Rev date: 2026-04-17**Validità della dichiarazione:**
dal 2026-04-24
fino al 2030-11-15**Validity of this declaration:**
from 2026-04-24
until 2030-11-15

Mirandola,

2026-04-23

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

Mirandola,

2026-04-17

Chiara Bergamini
Vice President Regulatory Affairs

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 I sterile	Rule 5
226110	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226112	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226114	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226116	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226208	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226210	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226212	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226214	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226216	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226218	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226306	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226308	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226310	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226312	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226314	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
226316	Actreen® Glyc Set	Box of 30	class I sterile	Rule 5
238108	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238110	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238112	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238114	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238116	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238118	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238208	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238210	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238212	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238214	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238216	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238218	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238306	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238308	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238310	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238312	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238314	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
238316	Actreen® Hi-Lite Cath	Box of 30	class I sterile	Rule 5
242110	Actreen® Hi-Lite Set	Box of 30	class I sterile	Rule 5
242112	Actreen® Hi-Lite Set	Box of 30	class I sterile	Rule 5
242114	Actreen® Hi-Lite Set	Box of 30	class I sterile	Rule 5
242116	Actreen® Hi-Lite Set	Box of 30	class I sterile	Rule 5
242118	Actreen® Hi-Lite Set	Box of 30	class I sterile	Rule 5
242210	Actreen® Hi-Lite Set	Box of 30	class I sterile	Rule 5
242212	Actreen® Hi-Lite Set	Box of 30	class I sterile	Rule 5
242214	Actreen® Hi-Lite Set	Box of 30	class I sterile	Rule 5
242216	Actreen® Hi-Lite Set	Box of 30	class I sterile	Rule 5
242218	Actreen® Hi-Lite Set	Box of 30	class I sterile	Rule 5
228108	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228110	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5

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228112	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228114	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228116	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228118	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228208	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228210	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228212	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228214	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228216	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228218	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228306	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228308	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228310	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228312	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228314	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228316	Actreen® Lite Cath	Box of 30	class I sterile	Rule 5
228108D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228110D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228112D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228114D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228116D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228118D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228208D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228210D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228212D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228214D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228216D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228218D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228306D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228308D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228310D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228312D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228314D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228316D	Actreen® Lite Cath	Box of 60	class I sterile	Rule 5
228008	Actreen® Mini Cath	Box of 30	class I sterile	Rule 5
228010	Actreen® Mini Cath	Box of 30	class I sterile	Rule 5
228012	Actreen® Mini Cath	Box of 30	class I sterile	Rule 5
228014	Actreen® Mini Cath	Box of 30	class I sterile	Rule 5
228016	Actreen® Mini Cath	Box of 30	class I sterile	Rule 5
2280126D	Actreen® Mini Cath	Box of 60	class I sterile	Rule 5
2280106D	Actreen® Mini Cath	Box of 60	class I sterile	Rule 5
239010	Actreen® Mini Set	Box of 30	class I sterile	Rule 5
239012	Actreen® Mini Set	Box of 30	class I sterile	Rule 5
239014	Actreen® Mini Set	Box of 30	class I sterile	Rule 5

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