

**Déclaration de Conformité
Declaration of Conformity**

Nous

We

B.BRAUN MEDICAL SAS26 Rue Armengaud
92210 Saint-Cloud
FRANCEdéclare par les présentes sous notre propre responsabilité
que le/les produit / s**Actreen Glyc Cath / Actreen Glyc Set / Actreen Lite Cath /
Actreen Mini Cath / Actreen Mini Set / Actreen Hi-Lite Cath /
Actreen Hi-Lite Set**Catheter stérile prêt à l'emploi indiqué pour le sondage urinaire
intermittent
(numéros d'article voir annexe I)

est / sont conformes à la directive suivante

Directive 93/42/CEE du Conseil du 14 juin 1993
concernant les dispositifs médicaux,
modifié par la directive 2007/47/CE**Procédure d'évaluation de la conformité**
selon l'annexe V
de la directive mentionnée ci-dessus**Classification**conformément à l'annexe IX de la directive susmentionnée:
Classe I stérile**Organisme notifié**TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Allemagne
Numéro d'identification 0123**Date du premier marquage CE**

2002-04

Valable jusqu'à

2024-05-26

hereby declare in our own responsibility
that the product/s**Actreen Glyc Cath / Actreen Glyc Set/ Actreen Lite
Cath / Actreen Mini Cath / Actreen Mini Set/ Actreen
Hi-Lite Cath / Actreen Hi-Lite Set**Ready to use sterile catheter indicated for intermittent
urinary catheterization
(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14 June 1993
concerning Medical Devices,
amended by Directive 2007/47/EG**Conformity assessment procedure**
according to annex V
of the Directive named above**Classification**according to annex IX of the Directive named above:
Class I sterile**Notified body**TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Date of first CE-marking**

2002-04

Valid until

2024-05-26

Nogent-le-Rotrou, 2022-12-06

Se référer à la dernière page pour les signatures

Nogent-le-Rotrou, 2022-12-06

See last page for signature

Déclaration de Conformité
Declaration of Conformity

Name: Jean-Philippe Bosle
Function: Quality Assurance and Regulatory Affairs
Manager

Name: Manuelle Schneider-Ponsot
Function: Director DORP BBMF

Effective

**Déclaration de Conformité
Declaration of Conformity**

Annexe I / Attachment I

Num.-Art. / Art. No.	Nom du produit / Product Name	Classe / Class
225108	Actreen Glyc Cath Tiemann / Box of 30	Is
225110	Actreen Glyc Cath Tiemann / Box of 30	Is
225112	Actreen Glyc Cath Tiemann / Box of 30	Is
225114	Actreen Glyc Cath Tiemann / Box of 30	Is
225116	Actreen Glyc Cath Tiemann / Box of 30	Is
225118	Actreen Glyc Cath Tiemann / Box of 30	Is
225208	Actreen Glyc Cath Nelaton / Box of 30	Is
225210	Actreen Glyc Cath Nelaton / Box of 30	Is
225212	Actreen Glyc Cath Nelaton / Box of 30	Is
225214	Actreen Glyc Cath Nelaton / Box of 30	Is
225216	Actreen Glyc Cath Nelaton / Box of 30	Is
225218	Actreen Glyc Cath Nelaton / Box of 30	Is
225306	Actreen Glyc Cath Nelaton / Box of 30	Is
225308	Actreen Glyc Cath Nelaton / Box of 30	Is
225310	Actreen Glyc Cath Nelaton / Box of 30	Is
225312	Actreen Glyc Cath Nelaton / Box of 30	Is
225314	Actreen Glyc Cath Nelaton / Box of 30	Is
225316	Actreen Glyc Cath Nelaton / Box of 30	Is
225108D	Actreen Glyc Cath Tiemann for Spain / Box of 60	Is
225110D	Actreen Glyc Cath Tiemann for Spain / Box of 60	Is
225112D	Actreen Glyc Cath Tiemann for Spain / Box of 60	Is
225114D	Actreen Glyc Cath Tiemann for Spain / Box of 60	Is
225116D	Actreen Glyc Cath Tiemann for Spain / Box of 60	Is
225118D	Actreen Glyc Cath Tiemann for Spain / Box of 60	Is
235208D	Actreen Glyc Cath Nelaton for Spain / Box of 60	Is
235210D	Actreen Glyc Cath Nelaton for Spain / Box of 60	Is
235212D	Actreen Glyc Cath Nelaton for Spain / Box of 60	Is
235214D	Actreen Glyc Cath Nelaton for Spain / Box of 60	Is
235216D	Actreen Glyc Cath Nelaton for Spain / Box of 60	Is
235218D	Actreen Glyc Cath Nelaton for Spain / Box of 60	Is
235306D	Actreen Glyc Cath Nelaton for Spain / Box of 60	Is
235308D	Actreen Glyc Cath Nelaton for Spain / Box of 60	Is
235310D	Actreen Glyc Cath Nelaton for Spain / Box of 60	Is
235312D	Actreen Glyc Cath Nelaton for Spain / Box of 60	Is
235314D	Actreen Glyc Cath Nelaton for Spain / Box of 60	Is
235316D	Actreen Glyc Cath Nelaton for Spain / Box of 60	Is
226108	Actreen Glyc Set Tiemann / Box of 30	Is
226110	Actreen Glyc Set Tiemann / Box of 30	Is
226112	Actreen Glyc Set Tiemann / Box of 30	Is
226114	Actreen Glyc Set Tiemann / Box of 30	Is
226116	Actreen Glyc Set Tiemann / Box of 30	Is
226208	Actreen Glyc Set Nelaton / Box of 30	Is
226210	Actreen Glyc Set Nelaton / Box of 30	Is
226212	Actreen Glyc Set Nelaton / Box of 30	Is

**Déclaration de Conformité
Declaration of Conformity**

226214	Actreen Glys Set Nelaton / Box of 30	Is
226216	Actreen Glys Set Nelaton / Box of 30	Is
226218	Actreen Glys Set Nelaton / Box of 30	Is
226306	Actreen Glys Set Nelaton / Box of 30	Is
226308	Actreen Glys Set Nelaton / Box of 30	Is
226310	Actreen Glys Set Nelaton / Box of 30	Is
226312	Actreen Glys Set Nelaton / Box of 30	Is
226314	Actreen Glys Set Nelaton / Box of 30	Is
226316	Actreen Glys Set Nelaton / Box of 30	Is
228108	Actreen Lite Cath Tiemann / Box of 30	Is
228110	Actreen Lite Cath Tiemann / Box of 30	Is
228112	Actreen Lite Cath Tiemann / Box of 30	Is
228114	Actreen Lite Cath Tiemann / Box of 30	Is
228116	Actreen Lite Cath Tiemann / Box of 30	Is
228118	Actreen Lite Cath Tiemann / Box of 30	Is
228208	Actreen Lite Cath Nelaton / Box of 30	Is
228210	Actreen Lite Cath Nelaton / Box of 30	Is
228212	Actreen Lite Cath Nelaton / Box of 30	Is
228214	Actreen Lite Cath Nelaton / Box of 30	Is
228216	Actreen Lite Cath Nelaton / Box of 30	Is
228218	Actreen Lite Cath Nelaton / Box of 30	Is
228306	Actreen Lite Cath Nelaton / Box of 30	Is
228308	Actreen Lite Cath Nelaton / Box of 30	Is
228310	Actreen Lite Cath Nelaton / Box of 30	Is
228312	Actreen Lite Cath Nelaton / Box of 30	Is
228314	Actreen Lite Cath Nelaton / Box of 30	Is
228316	Actreen Lite Cath Nelaton / Box of 30	Is
228108D	Actreen Lite Cath Tiemann for Spain/ Box of 60	Is
228110D	Actreen Lite Cath Tiemann for Spain/ Box of 60	Is
228112D	Actreen Lite Cath Tiemann for Spain/ Box of 60	Is
228114D	Actreen Lite Cath Tiemann for Spain/ Box of 60	Is
228116D	Actreen Lite Cath Tiemann for Spain/ Box of 60	Is
228118D	Actreen Lite Cath Tiemann for Spain/ Box of 60	Is
228208D	Actreen Lite Cath Nelaton for Spain/ Box of 60	Is
228210D	Actreen Lite Cath Nelaton for Spain/ Box of 60	Is
228212D	Actreen Lite Cath Nelaton for Spain/ Box of 60	Is
228214D	Actreen Lite Cath Nelaton for Spain/ Box of 60	Is
228216D	Actreen Lite Cath Nelaton for Spain/ Box of 60	Is
228218D	Actreen Lite Cath Nelaton for Spain/ Box of 60	Is
228306D	Actreen Lite Cath Nelaton for Spain/ Box of 60	Is
228308D	Actreen Lite Cath Nelaton for Spain/ Box of 60	Is
228310D	Actreen Lite Cath Nelaton for Spain/ Box of 60	Is
228312D	Actreen Lite Cath Nelaton for Spain/ Box of 60	Is
228314D	Actreen Lite Cath Nelaton for Spain/ Box of 60	Is
228316D	Actreen Lite Cath Nelaton for Spain/ Box of 60	Is
228008	Actreen Mini Cath Nelaton / Box of 30	Is
228010	Actreen Mini Cath Nelaton / Box of 30	Is
228012	Actreen Mini Cath Nelaton / Box of 30	Is

Déclaration de Conformité
Declaration of Conformity

228014	Actreen Mini Cath Nelaton / Box of 30	Is
228016	Actreen Mini Cath Nelaton / Box of 30	Is
2280106D	Actreen Mini Cath Nelaton for Spain / Box of 60	Is
2280126D	Actreen Mini Cath Nelaton for Spain / Box of 60	Is
2280146D	Actreen Mini Cath Nelaton for Spain / Box of 60	Is
239008	Actreen Mini Set Nelaton / Box of 30	Is
239010	Actreen Mini Set Nelaton / Box of 30	Is
239012	Actreen Mini Set Nelaton / Box of 30	Is
239014	Actreen Mini Set Nelaton / Box of 30	Is
238108	Actreen Hi-Lite Cath Tiemann / Box of 30	Is
238110	Actreen Hi-Lite Cath Tiemann / Box of 30	Is
238112	Actreen Hi-Lite Cath Tiemann / Box of 30	Is
238114	Actreen Hi-Lite Cath Tiemann / Box of 30	Is
238116	Actreen Hi-Lite Cath Tiemann / Box of 30	Is
238118	Actreen Hi-Lite Cath Tiemann / Box of 30	Is
238208	Actreen Hi-Lite Cath Nelaton / Box of 30	Is
238210	Actreen Hi-Lite Cath Nelaton / Box of 30	Is
238212	Actreen Hi-Lite Cath Nelaton / Box of 30	Is
238214	Actreen Hi-Lite Cath Nelaton / Box of 30	Is
238216	Actreen Hi-Lite Cath Nelaton / Box of 30	Is
238218	Actreen Hi-Lite Cath Nelaton / Box of 30	Is
238306	Actreen Hi-Lite Cath Nelaton / Box of 30	Is
238308	Actreen Hi-Lite Cath Nelaton / Box of 30	Is
238310	Actreen Hi-Lite Cath Nelaton / Box of 30	Is
238312	Actreen Hi-Lite Cath Nelaton / Box of 30	Is
238314	Actreen Hi-Lite Cath Nelaton / Box of 30	Is
238316	Actreen Hi-Lite Cath Nelaton / Box of 30	Is
242110	Actreen Hi-Lite Set Tiemann / Box of 30	Is
242112	Actreen Hi-Lite Set Tiemann / Box of 30	Is
242114	Actreen Hi-Lite Set Tiemann / Box of 30	Is
242116	Actreen Hi-Lite Set Tiemann / Box of 30	Is
242118	Actreen Hi-Lite Set Tiemann / Box of 30	Is
242210	Actreen Hi-Lite Set Nelaton / Box of 30	Is
242212	Actreen Hi-Lite Set Nelaton / Box of 30	Is
242214	Actreen Hi-Lite Set Nelaton / Box of 30	Is
242216	Actreen Hi-Lite Set Nelaton / Box of 30	Is
242218	Actreen Hi-Lite Set Nelaton / Box of 30	Is

Title: 078-001-1-7.1-Actreen Initiator: Estelle ? Rapine

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

UserName: Rapine, Estelle (rapiesfr)
Title: Regulatory Affairs Assistant
Date: Friday, 09 December 2022, 11:30 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Bosle, Jean-Philippe (bosljejr)
Title: Quality Director
Date: Wednesday, 14 December 2022, 09:20 W. Europe Daylight Time
Meaning: Approve Document

UserName: Schneider-Ponsot, Manuelle (schnmafr)
Title: Quality Director / Safety Officer / Resp Pharmacist
Date: Thursday, 15 December 2022, 09:28 W. Europe Daylight Time
Meaning: Approve Document
