

Déclaration de Conformité **Declaration of Conformity**

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Nous

B.BRAUN MEDICAL SAS 26 rue Armengaud 92210 Saint-Cloud

FRANCE

déclare par les présentes sous notre propre responsabilité que le/les produit / s

Actreen Glys Cath / Actreen Glys 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 jusque 2023-10-01

Nogent-le-Rotrou, 2018-10-01

Name: Priscilla CHEDMAIL

Function: Regulatory Affairs Officer

hereby declare in our own responsibility that the product/s

Actreen Glys Cath / Actreen Glys 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 2023-10-01

Nogent-le-Rotrou, 2018-10-01

Name: Emmanuel DUFY

Function: Quality Assurance Manager fective



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Annexe I / Attachement I

NumArt. / Art. No.	Nom du produit / Product Name	Classe / Class
225108	Actreen Glys Cath Tiemann / Box of 30	ls
225110	Actreen Glys Cath Tiemann / Box of 30	ls
225112	Actreen Glys Cath Tiemann / Box of 30	ls
225114	Actreen Glys Cath Tiemann / Box of 30	ls
225116	Actreen Glys Cath Tiemann / Box of 30	ls
225118	Actreen Glys Cath Tiemann / Box of 30	ls
225208	Actreen Glys Cath Nelaton / Box of 30	ls
225210	Actreen Glys Cath Nelaton / Box of 30	ls
225212	Actreen Glys Cath Nelaton / Box of 30	ls
225214	Actreen Glys Cath Nelaton / Box of 30	ls
225216	Actreen Glys Cath Nelaton / Box of 30	ls
225218	Actreen Glys Cath Nelaton / Box of 30	ls
225306	Actreen Glys Cath Nelaton / Box of 30	ls
225308	Actreen Glys Cath Nelaton / Box of 30	ls
225310	Actreen Glys Cath Nelaton / Box of 30	ls
225312	Actreen Glys Cath Nelaton / Box of 30	ls
225314	Actreen Glys Cath Nelaton / Box of 30	ls
225316	Actreen Glys Cath Nelaton / Box of 30	ls
225108D	Actreen Glys Cath Tiemann for Spain / Box of 60	ls
225110D	Actreen Glys Cath Tiemann for Spain / Box of 60	ls
225112D	Actreen Glys Cath Tiemann for Spain / Box of 60	ls
225114D	Actreen Glys Cath Tiemann for Spain / Box of 60	ls
225116D	Actreen Glys Cath Tiemann for Spain / Box of 60	ls
225118D	Actreen Glys Cath Tiemann for Spain / Box of 60	ls
235208D	Actreen Glys Cath Nelaton for Spain / Box of 60	ls
235210D	Actreen Glys Cath Nelaton for Spain / Box of 60	ls
235212D	Actreen Glys Cath Nelaton for Spain / Box of 60	ls
235214D	Actreen Glys Cath Nelaton for Spain / Box of 60	ls
235216D	Actreen Glys Cath Nelaton for Spain / Box of 60	ls
235218D	Actreen Glys Cath Nelaton for Spain / Box of 60	Is
235306D	Actreen Glys Cath Nelaton for Spain / Box of 60	ls
235308D	Actreen Glys Cath Nelaton for Spain / Box of 60	ls
235310D	Actreen Glys Cath Nelaton for Spain / Box of 60	ls
235312D	Actreen Glys Cath Nelaton for Spain / Box of 60	ls
235314D	Actreen Glys Cath Nelaton for Spain / Box of 60	ls
235316D	Actreen Glys Cath Nelaton for Spain / Box of 60	ls
226108	Actreen Glys Set Tiemann / Box of 30	ls
226110	Actreen Glys Set Tiemann / Box of 30	ls
226112	Actreen Glys Set Tiemann / Box of 30	ls
226114	Actreen Glys Set Tiemann / Box of 30	ls
226116	Actreen Glys Set Tiemann / Box of 30	ls
226208	Actreen Glys Set Nelaton / Box of 30	ls
226210	Actreen Glys Set Nelaton / Box of 30	ls
226212	Actreen Glys Set Nelaton / Box of 30	ls
226214	Actreen Glys Set Nelaton / Box of 30	
226216	Actreen Glys Set Nelaton / Box of 30	Effective

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226218	Actreen Glys Set Nelaton / Box of 30	ls
226306	Actreen Glys Set Nelaton / Box of 30	ls
226308	Actreen Glys Set Nelaton / Box of 30	
226310	Actreen Glys Set Nelaton / Box of 30	ls
226312	Actreen Glys Set Nelaton / Box of 30	ls
226314	Actreen Glys Set Nelaton / Box of 30	ls
226314		ls
	Actreen Glys Set Nelaton / Box of 30	ls
228108	Actreen Lite Cath Tiemann / Box of 30	ls
228110	Actreen Lite Cath Tiemann / Box of 30	ls
228112	Actreen Lite Cath Tiemann / Box of 30	ls
228114	Actreen Lite Cath Tiemann / Box of 30	ls
228116	Actreen Lite Cath Tiemann / Box of 30	ls
228118	Actreen Lite Cath Tiemann / Box of 30	ls
228208	Actreen Lite Cath Nelaton / Box of 30	ls
228210	Actreen Lite Cath Nelaton / Box of 30	ls
228212	Actreen Lite Cath Nelaton / Box of 30	ls
228214	Actreen Lite Cath Nelaton / Box of 30	ls
228216	Actreen Lite Cath Nelaton / Box of 30	ls
228218	Actreen Lite Cath Nelaton / Box of 30	ls
228306	Actreen Lite Cath Nelaton / Box of 30	ls
228308	Actreen Lite Cath Nelaton / Box of 30	ls
228310	Actreen Lite Cath Nelaton / Box of 30	ls
228312	Actreen Lite Cath Nelaton / Box of 30	ls
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	ls
228114D	Actreen Lite Cath Tiemann for Spain/ Box of 60	Is
228116D	Actreen Lite Cath Tiemann for Spain/ Box of 60	ls
228118D	Actreen Lite Cath Tiemann for Spain/ Box of 60	ls
228208D	Actreen Lite Cath Nelaton for Spain/ Box of 60	ls
228210D	Actreen Lite Cath Nelaton for Spain/ Box of 60	ls
228212D	Actreen Lite Cath Nelaton for Spain/ Box of 60	ls
228214D	Actreen Lite Cath Nelaton for Spain/ Box of 60	ls
228216D	Actreen Lite Cath Nelaton for Spain/ Box of 60	ls
228218D	Actreen Lite Cath Nelaton for Spain/ Box of 60	ls
228306D	Actreen Lite Cath Nelaton for Spain/ Box of 60	ls
228308D	Actreen Lite Cath Nelaton for Spain/ Box of 60	ls
228310D	Actreen Lite Cath Nelaton for Spain/ Box of 60	ls
228310D 228312D	Actreen Lite Cath Nelaton for Spain/ Box of 60	
228314D	Actreen Lite Cath Nelaton for Spain/ Box of 60	ls
		ls
228316D	Actreen Lite Cath Nelaton for Spain/ Box of 60	ls
228008	Actreen Mini Cath Nelaton / Box of 30	ls
228010	Actreen Mini Cath Nelaton / Box of 30	ls
228012	Actreen Mini Cath Nelaton / Box of 30	ls
228014	Actreen Mini Cath Nelaton / Box of 30	ls
228016	Actreen Mini Cath Nelaton / Box of 30	Effectiv
2280106D	Actreen Mini Cath Nelaton for Spain / Box of 60	ls

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