

**Déclaration de Conformité**  
**Declaration of Conformity**

Nous

We

**B.BRAUN MEDICAL SAS**26 Rue Armengaud  
92210 Saint-Cloud  
FRANCEdéclare par les présentes sous notre propre responsabilité  
que le/les produit / s**Actreen Glyc Luer Lock**Catheter stérile prêt à l'emploi indiqué pour le sondage urinaire  
intermittent et pour l'instillation vésicale  
(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 sterile**Organisme notifié**TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Allemagne  
Numéro d'identification 0123**Date du premier marquage CE**

2005-03

**Valable jusqu'à**

2024-05-26

Nogent-le-Rotrou, 2022-12-06

*Se référer à la dernière page pour les signatures*Name: Jean-Philippe Bosle  
Function: Quality Assurance and Regulatory Affairs  
Managerhereby declare in our own responsibility  
that the product/s**Actreen Glyc Luer Lock**Ready for use sterile catheter indicated for intermittent  
urinary catheterization and for vesical instillation  
(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**

2005-03

**Valid until**

2024-05-26

Nogent-le-Rotrou, 2022-12-06

*See last page for signature*Name: Manuelle Schneider-Ponsot  
Function: Director DORP BBMF**Effective**

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## Annexe I / Attachment I

<b>Num.-Art. / Art. No.</b>	<b>Nom du produit / Product Name</b>	<b>Classe / Class</b>
227408	Actreen Glyc Luer Lock Tiemann / Box of 10	Is
227410	Actreen Glyc Luer Lock Tiemann / Box of 10	Is
227412	Actreen Glyc Luer Lock Tiemann / Box of 10	Is
227414	Actreen Glyc Luer Lock Tiemann / Box of 10	Is
227416	Actreen Glyc Luer Lock Tiemann / Box of 10	Is
227208	Actreen Glyc Luer Lock Nelaton / Box of 10	Is
227210	Actreen Glyc Luer Lock Nelaton / Box of 10	Is
227212	Actreen Glyc Luer Lock Nelaton / Box of 10	Is
227214	Actreen Glyc Luer Lock Nelaton / Box of 10	Is
227216	Actreen Glyc Luer Lock Nelaton / Box of 10	Is
227308	Actreen Glyc Luer Lock Nelaton / Box of 10	Is
227310	Actreen Glyc Luer Lock Nelaton / Box of 10	Is
227312	Actreen Glyc Luer Lock Nelaton / Box of 10	Is
227314	Actreen Glyc Luer Lock Nelaton / Box of 10	Is
227316	Actreen Glyc Luer Lock Nelaton / Box of 10	Is

**Effective**

Title: 078-003-7.1-Actreen Glys Luer Lock 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, 11:40 W. Europe Daylight Time  
Meaning: Document signed as Author

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UserName: Schneider-Ponsot, Manuelle (schnmafr)  
Title: Quality Director / Safety Officer / Resp Pharmacist  
Date: Tuesday, 13 December 2022, 08:32 W. Europe Daylight Time  
Meaning: Approve Document

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UserName: Bosle, Jean-Philippe (bosljefr)  
Title: Quality Director  
Date: Wednesday, 14 December 2022, 09:29 W. Europe Daylight Time  
Meaning: Approve Document

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