

**Déclaration de Conformité  
Declaration of Conformity**Effective Date : **last date**  
of signature

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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**Cystofix / Cystofix SG**Set de ponction, set de rechange et set de rechange et dilatation  
destinés au cathétérisme percutané sus-pubien.  
(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 II.3  
de la directive mentionnée ci-dessus**Classification**conformément à l'annexe IX de la directive susmentionnée:  
Classe IIb sterile**Organisme notifié**TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Allemagne  
Numéro d'identification 0123**Date du premier marquage CE**  
2013-12**Valable jusque**  
2024-05-26hereby declare in our own responsibility  
that the product/s**Cystofix / Cystofix SG**Puncture set, exchange set or dilation exchange set for  
suprapubic percutaneous catheter insertion  
(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 II.3  
of the Directive named above**Classification**according to annex IX of the Directive named above:  
Class IIb sterile**Notified body**TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Germany  
Identification number 0123**Date of first CE-marking**  
2013-12**Valid until**  
2024-05-26

Nogent-le-Rotrou, 2022-12-06

Nogent-le-Rotrou, 2022-12-06

*Se référer à la dernière page pour les signatures**See last page for signature*Name: Jean-Philippe Bosle  
Function: Quality Assurance and Regulatory Affairs  
ManagerName: 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>
4450512	Cystofix Dilatation Set / Box of 5	IIb
4450514	Cystofix Dilatation Set / Box of 5	IIb
4450516	Cystofix Dilatation Set / Box of 5	IIb
4450010	Cystofix Exchange Set / Box of 5	IIb
4450012	Cystofix Exchange Set / Box of 5	IIb
4450014	Cystofix Exchange Set / Box of 5	IIb
4450016	Cystofix Exchange Set / Box of 5	IIb
4450712	Cystofix Exchange Set / Box of 5	IIb
4450714	Cystofix Exchange Set / Box of 5	IIb
4450716	Cystofix Exchange Set / Box of 5	IIb
4450718	Cystofix Exchange Set / Box of 5	IIb
4450720	Cystofix Exchange Set / Box of 5	IIb
4450812	Cystofix Exchange Set / Box of 1	IIb
4450814	Cystofix Exchange Set / Box of 1	IIb
4450816	Cystofix Exchange Set / Box of 1	IIb
4450818	Cystofix Exchange Set / Box of 1	IIb
4450820	Cystofix Exchange Set / Box of 1	IIb
4450410	Cystofix SG Set/ Box of 5	IIb
4450412	Cystofix SG Set/ Box of 5	IIb
4450414	Cystofix SG Set/ Box of 5	IIb
4450416	Cystofix SG Set/ Box of 5	IIb

**Effective**

Title: 080-006-7.1-Cystofix 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, 11:47 W. Europe Daylight Time  
Meaning: Document signed as Author

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UserName: Bosle, Jean-Philippe (bosljejr)  
Title: Quality Director  
Date: Wednesday, 14 December 2022, 09:25 W. Europe Daylight Time  
Meaning: Approve Document

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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

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