

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

Nous

We

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

déclare 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 stérile

**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**  
2023-09-17

Nogent-le-Rotrou, 2018-09-17

Name: Priscilla CHEDMAIL  
Function: Regulatory Affairs Officer

hereby 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**  
2023-09-17

Nogent-le-Rotrou, 2018-09-17

Name: Emmanuel DUFY  
Function: Quality Assurance Manager

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

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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                   |