

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

Page: 1 of 2

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**Urinocol**Poches adhésives et stériles, utilisées en pédiatrie pour le recueil  
des urines dans le cadre de la diurèse ou pour analyses  
biochimiques, cytologiques et bactériologiques.  
(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**  
2006-06**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**Urinocol**Adhesive and sterile bag for urine collection, used in  
paediatrics within the context of diuresis or for  
biochemical, cytological and bacteriological examinations  
(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**  
2006-06**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>
227550	Urinocol Paediatric Closed, sterile pouch / Box of 100	I sterile
227549	Urinocol Paediatric Closed, sterile pouch / Box of 20	I sterile
227560	Urinocol Paediatric Closed, sterile pouch / Box of 100	I sterile
227559	Urinocol Paediatric Closed, sterile pouch / Box of 20	I sterile
227546	Urinocol Paediatric Open, sterile pouch / Box of 50	I sterile
227547	Urinocol Paediatric Open, sterile pouch / Box of 50	I sterile
227566	Urinocol Paediatric Open, sterile pouch / Box of 50	I sterile
227567	Urinocol Paediatric Open, sterile pouch / Box of 50	I sterile
227571	Urinocol Premature Sterile pouch / Box of 50	I sterile
227570	Urinocol Premature Sterile pouch / Box of 50	I sterile
227573	Urinocol Premature Sterile pouch with extension line / Box of 50	I sterile
227572	Urinocol Premature Sterile pouch with extension line / Box of 50	I sterile

**Effective**

Title: 275-001-7.1-Urinocol 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, 11:41 W. Europe Daylight Time  
Meaning: Document signed as Author  
=====

UserName: Bosle, Jean-Philippe (bosljejr)  
Title: Quality Director  
Date: Wednesday, 14 December 2022, 09:27 W. Europe Daylight Time  
Meaning: Approve Document  
=====

UserName: Schneider-Ponsot, Manuelle (schnmafr)  
Title: Quality Director / Safety Officer / Resp Pharmacist  
Date: Thursday, 15 December 2022, 09:26 W. Europe Daylight Time  
Meaning: Approve Document  
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