

**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
FRANCE

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

Be 1 Et Flexima-Softima 3S Be 1
Poches de recueil fermées Et Supports 2-pièces pour
colostomisés
(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 VII
de la directive mentionnée ci-dessus

Classification
conformément à l'annexe IX de la directive
susmentionnée: Classe I non sterile

Date du premier marquage CE
2018-05

Valable jusque
2024-03-01

hereby declare in our own responsibility
that the product/s

Be 1 Et Flexima-Softima 3S Be 1
2-piece Closed pouches Et base Plates for colostomates
(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/EC

Conformity assessment procedure
according to annex VII
of the Directive named above

Classification
according to annex IX of the Directive named
above:
Class I non sterile

Date of first CE-marking
2018-05

Valid until
2024-03-01

Saint-Jean-de-Luz, 2019-03-01

Saint-Jean-de-Luz, 2019-03-01

Name: Isabelle DESPLAT
Function: Regulatory Affairs Officer

Name: Ludovic ETCHEVERRY
Function: Quality and Regulatory Affairs Manager

**Effective**

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Annexe I / Attachment I

Num.-Art. / Art. No.	Nom du produit / Product Name	Classe / Class
936516	Flexima®-Softima® 3S Be1 Base Plate diameter 55/Cut-to-fit 15-40mm by 10 units	I non sterile
936616	Flexima®-Softima® 3S Be1 Base Plate diameter 65/Cut-to-fit 15-50mm by 10 units	I non sterile
936517	Flexima®-Softima® 3S Be1 Base Plate diameter 55/Cut-to-fit 15-40mm by 5 units	I non sterile
936617	Flexima®-Softima® 3S Be1 Base Plate diameter 65/Cut-to-fit 15-50mm by 5 units	I non sterile
9350155	Be 1 closed pouch diameter 55mm by 10 units	I non sterile
9350355	Be 1 closed pouch diameter 55mm by 30 units	I non sterile
9350165	Be 1 closed pouch diameter 65mm by 10 units	I non sterile
9350365	Be 1 closed pouch diameter 65mm by 30 units	I non sterile

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