

**Déclaration de Conformité UE
EU Declaration of Conformity**

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Nous

We

B. BRAUN MEDICAL SAS
SRN FR-MF-000000674
26 Rue Armengaud
92210 Saint-Cloud
FRANCE

déclarons par les présentes et sous notre seule
responsabilité que le/les produit/s

Basic-UDI-DI : 03923900000018322

Urimed® Vision
Urimed® Vision Standard / Urimed® Vision Short /
Urimed® Vision Ultra

Transparent Self-Adhering Male External Catheter
(numéros d'article voir annexe I)

Fabriqué à
Davol Surgical Innovations
S.A. de C.V.
Gral. Roberto Fierro No. 6408
Parque Industrial Aeropuerto
Ciudad Juarez
Chihuahua
C.P. 32685 Mexico

est / sont conforme(s) aux exigences du Règlement
(UE) 2017/745 relatif aux dispositifs médicaux amendé
par le Règlement (UE) 2020/561

Procédure d'évaluation de la conformité
selon l'annexe IV
du Règlement mentionné ci-dessus

Classification
conformément à l'annexe VIII du Règlement
susmentionné : (voir Annexe I)

Date du premier marquage CE
ou premier numéro de lot
2000-10

Valable jusqu'au
2026-12-31
suivant notre Certificat ISO (*dispositifs de classe I*)

hereby declare under our own responsibility that the
product/s

Basic-UDI-DI : 03923900000018322

Urimed® Vision
Urimed® Vision Standard / Urimed® Vision Short /
Urimed® Vision Ultra

Transparent Self-Adhering Male External Catheter
(article numbers see attachment I)

Manufactured in
Davol Surgical Innovations
S.A. de C.V.
Gral. Roberto Fierro No. 6408
Parque Industrial Aeropuerto
Ciudad Juarez
Chihuahua
C.P. 32685 Mexico

is/are in compliance with the requirements of the
Medical Device Regulation (EU) 2017/745 amended by
Regulation (EU) 2020/561

Conformity Assessment Procedure
according to annex IV
of the Regulation named above

Classification
according to annex VIII of the Regulation named above:
(See Attachment I)

Date of first EC-marking
or first lot number
2000-10

Valid until
2026-12-31
according to our valid ISO Certificate (*class I devices*)

Effective

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Annexe I / Attachment I

Référence / Article number	Designation	Classe / Class	Stérile/ Sterile	Basic-UDI-DI
IH2525	Urimed Vision Standard	I	N	03923900000018322
IH2529	Urimed Vision Standard	I	N	03923900000018322
IH2532	Urimed Vision Standard	I	N	03923900000018322
IH2536	Urimed Vision Standard	I	N	03923900000018322
IH2541	Urimed Vision Standard	I	N	03923900000018322
IH4525	Urimed Vision Short	I	N	03923900000018322
IH4529	Urimed Vision Short	I	N	03923900000018322
IH4532	Urimed Vision Short	I	N	03923900000018322
IH4536	Urimed Vision Short	I	N	03923900000018322
IH4541	Urimed Vision Short	I	N	03923900000018322
IH3525	Urimed Vision Ultra	I	N	03923900000018322
IH3529	Urimed Vision Ultra	I	N	03923900000018322
IH3532	Urimed Vision Ultra	I	N	03923900000018322
IH3536	Urimed Vision Ultra	I	N	03923900000018322
IH3541	Urimed Vision Ultra	I	N	03923900000018322
28625	Urimed Vision Standard	I	N	03923900000018322
28629	Urimed Vision Standard	I	N	03923900000018322
28632	Urimed Vision Standard	I	N	03923900000018322
28636	Urimed Vision Standard	I	N	03923900000018322
28641	Urimed Vision Standard	I	N	03923900000018322
28825	Urimed Vision Short	I	N	03923900000018322
28829	Urimed Vision Short	I	N	03923900000018322
28832	Urimed Vision Short	I	N	03923900000018322
28836	Urimed Vision Short	I	N	03923900000018322
28841	Urimed Vision Short	I	N	03923900000018322

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Annexe II / Attachment II: Spécifications communes/ Common specifications
N/A

Title: 274-004-7.1-Urimed Vision MDR Initiator: Priscilla ? Chapelier

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Chapelier, Priscilla (chapprfr)
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Meaning: Document signed as Author
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