

ATTESTATION CE / EC CERTIFICATE

Examen CE de la Conception (du produit) / EC Design Examination (of the product)

ANNEXE II point 4 de la directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II section 4 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant / Manufacturer

OCON MEDICAL Ltd

1 Ligad Center, 15 Hashdera Hamerkazit Street

MODIIN, 7171801 ISRAEL

Catégorie du(des) dispositif(s) / Device(s) category

Dispositifs intra-uterins

Intrauterine devices

Identification du(des) dispositif(s) / Identification of device(s)

IUB Ballerine

GMDN code: 46920

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) référencé(s) P602488, le(s) produit(s) énuméré(s) ci-dessus est (sont) conforme(s) aux exigences de l'annexe I de la directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file(s) referenced P602488, the product(s) comply(ies) with the requirements of the directive 93/42/EEC, annex 1

Début de validité / Effective date : **May 18th, 2020 (included)**

Valable jusqu'au / Expiry date : **May 25th, 2021 (included)**



DocuSigned by:

Beatrice Lys

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On behalf of the President

Béatrice LYS

Technical Director

Identification des dispositifs / Identification of devices

Medical Device Name	Size		Class
IUB™ Ballerine® Intrauterine Device	MINI: small size	12mm (+/-2mm)	III
	MIDI: medium size	15mm (+/-2mm)	

GMED	0459
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On behalf of the President
Béatrice LYS
Technical Director