

FOR.ME.SA.srl Via Canvelli,6 43015 Noceto (PR) Italia Tel. +39 0521.628482 Fax. +39 0521.620382 www.formesa.it

e-mail: info@formesa.it Cod. Fisc. e Part. IVA: IT01714420344 R.E.A. Parma: 173353

PEC: <u>formesa@arubapec.it</u> Cod. Mecc.: PR 017790





REG. N. 3685-A UNI EN ISO 9001:2008

DECLARATION OF CONFORMITY C€

According to the Standard 93/42/CEE, implemented in Italy with Legislative Decree D.Lgs. 24/02/1997, no. 46

As amended by Directive 2007/47/CE (implemented with Legislative Decree 25/01/2010 n. 37)

We, the undersigned representing FOR.ME.SA S.r.l., herewith declare under our sole responsibility that the Product called:

RUBBER PESSARY WITHOUT PIGMENT, in all mechanical sizes listed below:

Misura		Diam.: 50 mm	Diam.: 55 mm	Diam.: 60 mm	Diam.: 63 mm	Diam.: 65 mm	Diam.: 70 mm	Diam.: 75
	Diam.:75 mm	Diam.: 80 mm	Diam. :83 mm	Diam. :85 mm	Diam.89: mm.	Diam.:90 mm	Dism.:95 mm	Diam.:100
REF:		FOR.70.52050	FOR.70.52055	FOR.70.52060	FOR.70.52063	FOR.70.52065	FOR.70.52070	FOR.70.52075
REF:	FOR.70.51675	FOR.70.52080	FOR.70.52083	FOR.70.52085	FOR.70.52089	FOR.70.52090	FOR.70.52095	FOR.70.520100

Manufactured and Marketed by FOR.ME.SA S.r.l. itself, complies with all applicable provisions of the directive 93/42/CEE on Medical Devices

To that end, the Undersigned herewith grant and/or declare, always under their sole responsibility that:

- 1. the above mentioned Device must be considered as included in Class IIb according to the Rule 5 of Annex IX of the Directive 93/42/CEE;
- 2. the above mentioned Device meets, when specifically applicable, the fundamental requirements set out in Annex I of the Directive 93/42/CEE;
- 3. the above mentioned Device is marketed in agreement with EC Certificate N. MED 99/28 issued by Notified Body Kiwa Cermet (identification N. 0476) Via Cadriano, 23 40057 Granarolo dell'Emilia (BO), according to MDD 93/42/EEC.
- 4. the above mentioned Device IS NOT A MEASURING INSTRUMENT:
- 5. the above mentioned Device IS NOT MEANT FOR CLINICAL INVESTIGATIONS;
- 6. the above mentioned Device IS NOT DELIVERED IN A STERILE PACKING;
- 7. IT IS NOT ALLOWED to use the above mentioned Device for any purpose other than the intended use indicated by FOR.ME.SA S.r.l..
- 8. all documentation proving the conformity to the Directive 93/42/CEE will be made available to the relevant authorities for ten (10) years starting from the last date of production of the above mentioned Device.

The signee of this document is Mrs. Bizzi Desolina, having full legal authority to represent the Company within the European Community.

FOR.ME.SA. SRL Via F.IIi Canvelli, 6 43015 NOCETO (PR) COD.FISC. / P.IVA IT01714420344

Noceto, 14.09.2021

Place and date of issue

Signature and Company's Stamp

Decl. of Conf. 002 - Ed. 01 - Rev.: 6