




for.me.sa.
forniture medico sanitarie

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: formesa@arubapec.it
Cod. Mecc.: PR 017790



DECLARATION OF CONFORMITY 
*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:

SILICONE PESSARY, in all mechanical sizes listed below:

Size	Diam.: 50 mm	Diam.: 55 mm	Diam.: 60 mm	Diam.: 65 mm	Diam.: 70 mm	Diam.: 75 mm	Diam.: 80 mm	Diam.: 85
	Diam.:90 mm	Diam.: 95 mm	Diam. :100 mm					
REF:	FOR.70.51750	FOR.70.51755	FOR.70.51760	FOR.70.51765	FOR.70.51770	FOR.70.51775	FOR.70.51780	FOR.70.51785
	FOR.70.51790	FOR.70.51795	FOR.70.517100					

**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 9928 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.

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Noceto, 09.09.2021
Place and date of issue


Signature and Company's Stamp