INCAS
Medical Safety
Innovation

Subject: declaration of conformity of the medical device called "*Single-dose disinfectant containers with accessories*", produced by the company IN.CAS. S.r.l., with the essential requirements set out in Annex I of the European Directive 93/42 / EEC (and subsequent supplementary amendments - ref.: European Directive 2007/47 / EC) as required by Annex V and VII of the aforementioned Directive.

Hereby, the company IN.CAS. S.r.l., in the person of the General Manager Gianni Casamichele, manufacturer of the medical device called "Disinfectant containers with accessories", declares under his sole responsibility, the following:

"The products described in the Technical File " SINGLE-DOSE DISINFECTANT SYSTEM " meet all the essential requirements of Annex I of the European Directive 93/42 / EEC and subsequent supplementary amendments (ref.: European Directive 2007/47 / EC)".

Description	Code
COMPLETE SINGLE DAY KIT FOR CLOSED CIRCUIT ORGANIC LIQUID ASPIRATORS OF IN.CAS. RANGE FOR OPERATING ROOM, I.C.U., DEPARTMENTS OF WARD	KCM-SHOW01-S.O.
COMPLETE SINGLE DAY KIT FOR CLOSED CIRCUIT ORGANIC LIQUID ASPIRATORS OF IN.CAS. RANGE FOR ORTHOPEDICS	KCM-SHOW03-ORT.
COMPLETE SINGLE DAY KIT FOR CLOSED CIRCUIT ORGANIC LIQUID ASPIRATORS OF IN.CAS. RANGE FOR DIALYSIS / NEPHROLOGY	KCM-SHOW05-DIAL

For this purpose, the company IN.CAS. S.r.l. guarantees and declares the following:

1. the device in question complies with the applicable provisions of the European Directive 93/42 / EEC (and subsequent supplementary amendments - ref .: European Directive 2007/47 / EC).
2. the device in question is to be considered as belonging to class IIa, rule 15 of Annex IX of the European Directive 93/42 / EEC (and subsequent supplementary amendments - ref.: European Directive 2007/47 / EC).
3. the device in question is sold in a non-sterile package.
4. the manufacturer undertakes to keep and make available to the Notified Body n ° 0476 (Kiwa Cermet Italia SpA - Via Cadriano, 23 - 40057 Cadriano di Granarolo BO) and to the Competent Authority all the documentation relating to the product (technical file and production records) for a minimum period of 10 years from the last product manufacturing date.
5. the manufacturer has notified the competent Authority, following the placing on the market of the medical devices in question, the application of the post-sale surveillance procedure of the products as required by the European Directive 93/42 / EEC (and subsequent supplementary amendments - ref .: European Directive 2007/47 / EC).

DOSSOBUONO DI VILLAFRANCA, 12/06/2024

General Manager

IN.CAS. S.R.L. VIA STAFFALI 40/A 37062 DOSSOBUONO DI VILLAFRANCA (VR) ITALY

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