

DECLARATION OF CONFORMITY

Declaration of conformity relative to the device called flat reels *for plasma sterilization with length 70 mt., 100 mt. and 200 mt.*, manufactured by the company SOGEVA SRL, to the most important requirements as per the enclosed I of the 93/42/CEE directive, as prescribed by the enclosed VII of the above mentioned 93/42/CEE directive.

The underwritten company **SOGEVA SRL**, with its legal office in Borgosatollo (BS), Via del Canneto 10/18, manufacturing of the device called flat reels for plasma sterilization with length 70 mt., 100 mt. and 200 mt.

declares under its own responsibility that the above mentioned device satisfies all the provisions applicable in the 93/42/CEE directive on the Medical Devices.

For this reason, the underwritten guarantees and declares under its own responsibility as follow:

- the above mentioned device satisfies the most important requirements as per the enclosed I of the 93/42/CEE directive;
- the above mentioned device has to be considered of class I;
- the above mentioned device is traded in NON-STERILE packaging;
- the above mentioned device IS NOT A MEASURE INSTRUMENT;
- the above mentioned device IS NOT ADDRESSED TO CLINICAL RESEARCHES.

Rete/Dominio/NtServer/Dsogeva/Ministero della Sanità Sogeva 2006/declconftyvekFR

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Sogeva Srl
Presidente del Consiglio di Amministrazione
Enrico Sala

Responsabile Assicurazione Qualità
Dr. Gianluca Minutola