

DECLARATION OF CONFORMITY

Declaration of conformity relative to the device called BARRIER FILM, 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 BARRIER FILM,

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 2009/declconfBARRIERFILM

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**Sogeva Srl
Amministratore Delegato
Enrico Sala**

**Responsabile Assicurazione Qualità
Dr. Gianluca Minutola**