



DECLARATION OF CONFORMITY CE

Declaration of conformity for medical devices called

“DISPOSABLE PROTECTIVE FILM – type SEKUFILM A and SEKUFILM B”

Manufactured by company Sogeva S.r.l., following Encl. I of D. Lgs N° 46 dated 24 February 1997 and further issues, as stated on Encl. VII of the same D. Lgs.

The underwritten company Sogeva srl with its legal office in Borgosatollo (BS), Via del Canneto 10, manufacturer of the device called “DISPOSABLE PROTECTIVE FILM – type SEKUFILM A and SEKUFILM B”, declares, under its own responsibility that the above mentioned device satisfies the most important requirements as per the enclosed D. Lgs. N° 46 dated 24 February 1997 and further issues regarding 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 enclosed I of the above mentioned D. Lgs. 46/97;
- The above mentioned device has to be considered of Class I;
- The above mentioned device is not a measure instrument;
- The above mentioned device is not addressed to clinical researches;
- The above mentioned device is traded in non-sterile packaging and in single packing;
- The above mentioned device is manufactured in accordance with Quality System approved by CERMET following Encl. II of the above mentioned D. Lgs.

The underwritten company declares that Sogeva will keep the documents regarding Encl. VII of D. Lgs. 46/97 for five years starting from the latest date of production of the above mentioned device.

Borgosatollo, 3 July 2008

Dott. Gianluca Minutola