Object: **declaration of conformity of medical device called "WOVEN NON WOVEN PRODUCTS", manufactured by company SOGEVA S.r.l., with essential requirements as per Encl. I of European Directive 93/42/CEE (and further modifications and integrations – ref.: European Directive 2007/47/CE) as mentioned in Encl. VII of above mentioned Directive.**

With this letter company Sogeva S.r.l., in the name of General Manager Mr Enrico Sala, manufacturer of medical device called "WOVEN NON WOVEN PRODUCTS", declares the following:

"the products mentioned in Technical File "WOVEN NON WOVEN PRODUCTS" satisfy all essential requirements requested by Encl. I of European Directive 93/42/CEE and further modifications and integrations (ref.: European Directive 2007/47/CE)".

At this purpose company Sogeva S.r.l., grants and declares the following:

1. The device in object satisfies the disposition applicable as per European DIrective 93/42/CEE (and further modifications and integrations – ref.: European Directive 2007/47/CE).

2. The device in object is Class I, norm 1 of Encl. IX of European Directive 93/42/CEE (and further modifications and integrations – ref.: European Directive 2007/47/CE).

3. The device in object is sold in non-sterile packaging..

4. Manufacturer engages itself to keep and show to Competent Authority all the documents regarding the products (technical file and registration of production) for a minimum period of time of 10 years from last production date of the product.

5. Manufacturer has notified to competent Authority, following the introduction on the market of medical devices in object, the application of post-sale surveillance prodcedure of the products as requested by European Directive 93/42/CEE (and further modifications and integrations – ref.: European Directive 2007/47/CE).

Enrico Sala
(General Manager)

Ospitaletto, 15 novembre 2013

SOGEVA s.r.l.