Object: **declaration of conformity of medical device named "REELS AND POUCHES" manufactured by SOGEVA, with essential requirements as per Encl.I of 93/42/CEE Directive (and further modifications and integrations – with ref.: 2007/47/CE Directive) as required in Encl.VII of above mentioned Directive.**

With this letter, SOGEVA company, in the name of General Manager Enrico Sala, manufacturer of the medical device named "REELS AND POUCHES", declares the following:

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

At this purpose SOGEVA company grants and declares the following:

1. The device in object satisfies all the questions mentioned in 93/42/CEE European Directive (and further modifications and integrations – ref.: 2007/47/CE European Directive).

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

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

4. Manufacturer has informed Authority about the placing on the market of medical devices in object, about application of post-sales surveillance procedure of the product as required by 93/42/CEE European Directive (and further modifications and integrations– ref.: 2007/47/CE European Directive).

(General Manager)

OSPITALETTO, 19TH SEPTEMBER 2013