



**Object:** declaration of conformity of medical device named “CREPE PAPER”, 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 required 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 named “CREPE PAPER”, declares the following:

*“the products mentioned in Technical File “CREPE PAPER” satisfy all the essential requirements mentioned in Encl.I of European Directive 93/42/CEE and further modifications and integrations (ref.: European Directive 2007/47/CE)”.*

description	description
Green crepe paper	Blue SOFT SPECIAL crepe paper
Blue crepe paper	White SOFT SPECIAL crepe paper
White crepe paper	white SOFT crepe paper
Green SOFT SPECIAL crepe paper	Green 177

At this purpose company Sogeva S.r.l., 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 engages itself to keep and to show to Notify Body and Competent Authority all the documents relative to the product (technical file and registration of production) for a minimum period of 5 years from last production date.
5. 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).

**Enrico Sala**

Direzione Generale

Ospitaletto, 8 novembre 2013