

TECHNICAL FILE  
< LATEX SHEATHS >



**DECLARATION ON CONFORMITY**

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Pag. 1 / 1

**Object:** declaration of conformity of medical device called “LATEX SHEATHS”, 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 “LATEX SHEATHS”, declares the following:

*“the product mentioned in Technical File “LATEX SHEATHS” 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)”.*

Codes is the following:  
**GAUNI**

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

1. The device in object satisfy the dispositions applicable to 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 product (technical file and registration of production) for a minimum time of 10 years from last production date of the device.
5. Manufacturer has notified to competent Authority, following the introduction on the market of the medical device in object, the application of the post-sales surveillance procedure as requested by European Directive 93/42/CEE (and further modifications and integrations – ref.: European Directive 2007/47/CE).

  
**Enrico Sala**  
(General Manager)  
SOGEVA S.r.l.  
Via ...

Ospitaletto, 11.10.2013