

DECLARATION OF CONFORMITY

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Object: declaration of conformity of medical device called “SALIVA ROLLS”, 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 requested by 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 “SALIVA ROLLS”, declares the following:

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

Codes have been created with the following structure:

RLxxx where: RL identifies the family of “SALIVA ROLLS”, xxx number which identifies the product.

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

1. The device in object satisfy the dispositions applicable the device in object satisfies the dispositions applicable in 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 5 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. The 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 introduction on the market of medical device in object, the application of post-sale surveillance procedure 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)
Sogeva S.r.l.
Via... ..

Ospitaletto 10 ottobre 2013