

TECHNICAL FILE

< DENTAL USE DISPOSABLE PROTECTIVE
FILM FOR MEDICAL DEVICE >



DECLARATION OF CONFORMITY

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Pag. 1 di 1

Object: declaration of conformity of medical device called “DISPOSABLE PROTECTIVE FILM”, manufactured by company SOGEVA S.r.l., with essential requirements mentioned in 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 “DISPOSABLE PROTECTIVE FILM”, declares the following:

“the products mentioned in Technical File “DISPOSABLE PROTECTIVE FILM” 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 are the following:

SEKUFILM A: DISPOSABLE PROTECTIVE FILM width 5,5 cm and roll 45 cm;
SEKUFILM A: DISPOSABLE PROTECTIVE FILM width 4,5 cm and roll 45 cm

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

1. The device in object satisfy the dispositions 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 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 medical devices in object, the application of the post-sales 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)

Ospitaletto, 11.10.2013

SOGEVA S.r.l.
L. A. ospitaletto