Object: **declaration of conformity of medical device named "ASPIRATION TIPS", manufactured by the company SOGEVA S.r.l., with essential requirement 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 named "ASPIRATION TIPS", declares the following:

"the products described in Technical file "ASPIRATION TIPS" satisfy all essential requirements of Encl.I of European Directive 93/42/CEE and further modifications and integrations (ref.: European Directive 2007/47/CE)".

description	Code
Aspiration tip ∅ 11,0 mm and with L 14,5 cm	CANNULE MOD.A
Aspiration tip ∅ 16,0 mm and with L 13,0 cm	CANNULE MOD.B
Aspiration tip ∅ 11,0 mm and aspiration tip∅ 7,0 mm L 13,5 cm	CANNULE MOD.C
Adapter suitable for aspiration tip with ∅ 11,0 mm on handpieces with ∅ 16,0 mm	ADAT1
Adapter/reducer to transfer aspiration tips with ∅ 11,0 mm, disposable saliva ejectors and aspiration tips with ∅ 4,80 mm on handpieces with ∅ 16,0 mm	ADAT2
Adapter/reducer for disposable saliva ejectors and aspiration tips with ∅ 4,80 mm on handpieces with ∅ 11,0 mm	ADAT3

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

1. The device in object satisfy the norms requested by 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 Notify Body and Competent Authority all documents regarding the product (technical file and registration of the product) for a period of time of minimum 10 years from last date of production.
5. Manufacturer has notified to competent authority, following the issue on the market of the medical device in object, the application of post-sales surveillance 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, 14 novembre 2013