DECLARATION OF CONFORMITY

Re: declaration of conformity of the family of medical devices for odontostomatological use based on hyaluronic acid, manufactured by RICERFARMA S.r.l., with the essential requirements set out in Annex I to "Directive 93/42/EEC as amended by Directive 2007/47/EC", as prescribed by Annex VII to the said Directive 93/42/EEC as amended by Directive 2007/47/EC"; request for CE markings pursuant to "Directive 93/42/EEC as amended by Directive 2007/47/EC".

The applicant Ricerfarma S.r.l., a company holding ISO 13485 certification, whose registered office is located at Via Egadi 7, Milan (the manufacturer of the family of Hyaluronic acid-based Medical Devices for odontostomatological use and Hyaluronic acid-based Medical Devices for use in paediatric odontostomatology, having the tradenames Gengigel and Gengigel Teething (a complete list of devices will be found in Annex 1), hereinafter called "the GENGIGEL Family":

hereby declares, under its own responsibility, that the said family meets all the essential requirements laid down in Annex I to Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC.

For the said purpose it hereby guarantees and declares, under its own responsibility, as follows:

1. that the family of devices in question meets the applicable requirements of "Directive 93/42/EEC as amended by Directive 2007/47/EC";
2. that the family of devices in question can be deemed to belong to **Class IIa**;
3. that the family of devices in question is marketed in NON-STERILE packaging;
4. that the design of the devices making up the family in question meets the applicable requirements of the said Directive;
5. that the manufacturer undertakes to retain and hold at the disposal of the Notified Body the technical documentation specified in para. 3 of Annex V to "Directive 93/42/EEC as amended by Directive 2007/47/EC" for the period of five years from the last date of manufacture of the product;
6. that the devices making up the family in question are manufactured in accordance with the said annexed technical documentation;
7. that the manufacturer undertakes to introduce a systematic procedure to review the experience gained, as described in para. 4 of Annex V to "Directive 93/42/EEC, as amended by Directive 2007/47/EC";
8. that the manufacturing process is conducted in compliance with the company's Quality System, as required by Annex V to Directive 93/42/EEC and approved by IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A., notified body no. 0051.

Milan, 11/12/2018

Managing Director

Franco Macchi

ANNEX 1

Product category:	"Medical devices hyaluronic acid based products for stomatological dental use" (IIa) Medical devices hyaluronic acid based products for stomatological dental use in paediatrics (IIa)
Model:	**SL2001zzxxx** **SL2002zzxxx** **SL2003zzxxx** **SL2004zzxxx** **SL2005zzxxx** **SL2008zzxxx** **where:** SL2001 identifies Gel formulation SL2002 identifies Spray formulation SL2003 identifies Hydrogel formulation SL2004 identifies Gel Baby formulation SL2005 identifies Gel Junior formulation SL2008 identifies Gel Teething formulation zz identifies primary packs: 01 = tube PE 02 = sachet PI 03 = flacon PET xxx identifies volume between 1ml and 500 ml
Trademark:	GENGIGEL HYALUGEL ODDENT