

## EC DECLARATION OF CONFORMITY

**Manufacturer's name:** Anika Therapeutics S.r.l.

**Manufacturer's address:** Corso Stati Uniti, 4/U  
35127 Padova (PD) – Italy

**We declare under our sole responsibility that the device(s):**

**Name of device(s):** HYALOFAST  
*Presentations* 2x2 cm - 1 pad  
5x5 cm - 1 pad

**Product code(s) covered:**

144714F	HYALOFAST 1 PZ 2X2
144712F	HYALOFAST 1 PZ 2X2 TURKEY
144720F	HYALOFAST 1 PZ 2X2 SPAIN
144722F	HYALOFAST 1 PZ 5X5
144723F	HYALOFAST 1 PZ 5X5 TURKEY

**Classification (Class/Rule):** III (rule 8 – comma 3)  
(Annex IX, Dir. 93/42/EEC)

**Technical File reference:** TF 05

Conform with the Essential Requirements listed in Annex I of EC Directive 93/42/EEC and subsequent modifications, and to applicable harmonised standards, national standards or other normative documents referenced in the Technical File TF 05, Chapter 15.

**Notified Body:** GMED (CE 0459)

**Declaration valid until:** March 14<sup>th</sup>, 2021

This declaration is supported by:

- EC certificate of Type Examination (Annex III) no. 17003, rev. 13, issued by GMED on October 3<sup>rd</sup>, 2019;
- EC certificate of Approval of Production Quality Assurance System (Annex V) no. 9745, Rev.6, issued by GMED on February 20<sup>th</sup>, 2018.

**Place:** Padova (PD)



Carla Burlin  
Executive Director

**Date** October 16<sup>th</sup>, 2019

**Anika Therapeutics S.r.l.**

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