ANIKA THERAPEUTICS

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 14th, 2021**

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

Place: Padova (PD)

Date October 16th, 2019

Carla Burlin
Executive Director