To whom it may concern

DECLARATION OF CONFORMITY

The undersigned Rino Biasiolo, chief executive officer of Bioteck S.p.A, Via Enrico Fermi 49, 36057, Arcugnano, Italy

DECLARES

that the medical devices H42®, manufactured by Bioteck,

are compliant to the essential requirement 93/42/EEC directive Annex 1, and its following modifications and integrations,

and are classified, according to the annex IX of the same directive, rule 17, rule 8, hyphen 3, as **class III medical devices**.

THE NOTIFY BODY NUMBER IS: CE0477 - Eurofins Product Testing Italy srl

EC certificates Annex 2 section 4 numbers: EPT 0477.MDD. 20/4069.1, EPT 0477.MDD.20/4070.1

In faith,

Rino Biasiolo
Bioteck S.p.A. – CEO

Arcugnano, Italy, 25/05/2021

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