BIOTECK®
INNOVATING BIOMATERIALS

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 BIO-GEN®, 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. 19/3474.1, EPT 0477.MDD.19/3480.1

In faith,

Rino Biasiolo
Bioteck S.p.A. – CEO

Arcugnano, Italy, 25/05/2021

IMQ CERTIFIED QUALITY MANAGEMENT SYSTEM ISO 13485:2016

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