

10. Declaration of Conformity



DECLARATION OF CONFORMITY

MANUFACTURER **Bioservo AB**

ADDRESS **Torshamnsgatan 35, 164 40 Kista, Sweden**

DECLARE THAT THE FOLLOWING PRODUCT:

MODEL NAME **Carbonhand®**

TYPE **C0**

BASIC UDI-DI **735008216CH2DP**

INTENDED USE **Grasp assistance**

PRODUCT CLASSIFICATION **Class I (rule 1 & 13)**

SERIAL NUMBER

MAIN HARMONIZED STANDARDS

USED: **EN 60601-1, EN 60601-2**

FOLLOWING THE PROVISIONS OF DIRECTIVE: **2014/30/EU, 2012/19/EU, 2011/65/EU**

We hereby assure that the product above is in accordance with the European medical device regulation EU 2017/745.

PLACE AND DATE OF ISSUE **Kista 2024-02-20**

A handwritten signature in blue ink, appearing to read "Ibrahim Deregård".

Ibrahim Deregård
QA&RA

A handwritten signature in blue ink, appearing to read "Petter Bäckgren".

Petter
Bäckgren CEO