DECLARATION OF CONFORMITY

Object: Declaration of conformity of medical devices "N4SA" produced by HBW SRL to essential requirements and dispositions of the Directive 93/42/EEC (and further amendments-ref .: European Directive 2007/47/EC) as prescribed in the Annex VII of the Directive

The HBW srl, represented by Antonio Graziano with head office addressed in corso Galileo Ferraris 63, 10128, Torino (Italy), declares under our own responsibility that the following medical device named "N4SA":

- complies with essential requirements and dispositions of the Directive 93/42/EEC (and further amendments-ref .: European Directive 2007/47 / EC);
- the medical device is risk class I according to rule 12 of the Annex IX, Directive 93/42/EEC and further amendments (as amended by the Directive 2007/47/EC):
- the medical device is marketed in a no sterile condition;
- the manufacturer commits to keep and to make available to the Competent Authority all the product documentation (technical file and production records) for a minimum period of 10 years after the last product has been manufactured;
- the manufacturer has notified to the Competent Authority, following the decision on the medical device market in question, the application of postmarket product surveillance procedure as required by the Directive 93/42/EEC (and further amendments - ref .: European Directive 2007/47 / EC).

Turin, 09 April 2018

Antonio Graziano
(CEO of HBW)

H.B.W. srl
Via Pinerolo 101
10060 Candiolo
P.I. 10743650011