

Grassobbio, 2020/07/23

EC DECLARATION OF CONFORMITY

Delcon S.r.l.

Headquarters: via Matteucci 25/27 20862 Arcore (MB) and

Factory: via Zanica 19/F/I 24050 Grassobbio (BG),

as the manufacturer, declares that the product

Model: MacoPress Smart, Automatic blood component extractor

Type: MAC2.BR.LAN, MAC2.BR.WIFI, MAC2.BI.LAN, MAC2.BI.WIFI, MAC2.BI.WFRF

manufactured for: MACOPHARMA S.A.S.
Rue Lorthiois, 59420 MOUVAUX (FRANCE)



Complies with the technical requirements of the following standards:

- **SAFETY:** IEC 60601-1 (3rd Ed.) + A1, CAN/CSA-C22.2 No. 60601-1:08, ANSI/AAMI ES 60601-1:2005/A2:2010, IEC 61010-1:2010 AMD1:2016, UL 61010-1 (3rd Ed.) Am.1, CAN/CSA C22.2 No. 61010-1 + Amd 1
- **EMC:** IEC 60601-1-2:2014 (Fourth Edition)

The product meets the applicable provisions of the Medical Device Directive 93/42/EEC (implemented in Italy through legislative decree 24/02/1997 no. 46) and subsequent amendments provided by Directive 2007/47/EC (implemented in Italy through Legislative Decree of 25/01/2010 no. 37) and complies with the essential requirements of Annex I. This EC Declaration is made in accordance with Annex VII. The product is in Class I, according to Annex IX, rule 1 and rule 12 of the same Medical Devices Directive.

Valid from serial number 5018020.

For Delcon S.r.l.



Barbara Sala, **CEO**
Rev.: 9/0/2020