

## EC DECLARATION OF CONFORMITY

**The manufacturer:** DELCON S.r.l.  
**Address:** Via Matteucci, 25/27  
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### Declares that the Product

**Model:** **MacoPressSmart®** - Automatic blood component extractor

**Types:** MAC.DB.LAN (9MPSEVOLAN), MAC.DB.WIFI (9MPSEVOWIFI),  
MAC.DB.485 (9MPSEVO485), MAC.DB.LAN.NA  
(9MPSEVOLANNA), MAC.DB.WIFI.NA (9MPSEVOWIFINA),  
MAC.DB.485.NA (9MPSEVO485NA).

**Manufactured for :** **MACOPHARMA S.A.**  
**Rue Lorthiois**  
**59420 MOUVAUX (FRANCE)**

Complies with the technical requirements of the following European Standards:

**SAFETY:** IEC/EN 60601-1, 3<sup>rd</sup> Ed.  
IEC/EN 61010-1, 2<sup>nd</sup> Ed.  
UL 61010-1 2<sup>nd</sup> Ed.  
CAN/CSA C22.2 No. 61010-1 +G11 2<sup>nd</sup> Ed.  
IEC/EN 62304 1<sup>st</sup> Ed.

**EMC:** IEC/EN 60601-1-2, 3<sup>rd</sup> Ed.  
IEC/EN 61326, 1<sup>st</sup> Ed.

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 of the same Medical Devices Directive. The product meets also the applicable parts of the directive on machinery 2006/42/EC.

**First Issue :** March 21, 2012 from serial number 2529012

Arcore, March 21, 2012

Signed:

Norberto SALA  
(Managing Director)

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