

Grassobbio, yyyy/mm/dd

EU DECLARATION OF CONFORMITY

Delcon S.r.l.

Headquarters and Factory: via Zanica 19/F/I 24050 Grassobbio (BG)
SRN (Single Registration Number): IT-MF-000014234

as the manufacturer, declares that the product:

Model: HemoMxix 3
Description: Blood collection monitor
Ref: HMIX3.LAN, HMIX3.LAN.RFID, HMIX3.WIFI, HMIX3.WIFI.RFID
DMR Rev: x.x
DHF Rev: x.x
Basic UDI-DI: 803392853MIXEQ
Intended purpose: Blood collection monitor to perform whole blood collection from donor
Risk class: I (according to MDR 2017/745, Annex VIII - Rule 1, 13)

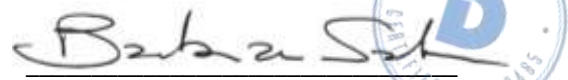
- Is in conformity with the Regulation MDR 2017/745 and with the Directive 2006/42
- Complies with the technical requirements of the following standards:

Safety: IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC
60601-1: 2012
EMC: IEC 60601-1-2:2014

This EU Declaration of Conformity is edited according to the Regulation MDR 2017/745 Annex IV and it is issued under the sole responsibility of Delcon S.r.l.

This EU Declaration of Conformity is valid for the serial number from 13xxxxxy to 13xxxxxy.

For Delcon S.r.l.



Barbara Sala
Chief Executive Officer

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