

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):* waiting for communication from Eudamed

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: 803392853MIXEGQ  
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 13xxxxyy.

For Delcon S.r.l.



Barbara Sala

Chief Executive Officer

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