EU DECLARATION OF CONFORMITY
IZJAVA EU O SKLADNOSTI

1. Product Range: / *Razred proizvedenih:* **MALLYA G**
   Basic UDI-DI: / *Osnovni UDI-DI:* **37014091 - Connected-MD43**
   Product technical file: / *Tehnična dokumentacija proizvedenih:* **TF_STUART_GROW**
   GMDN : **36862 : Patient monitoring system module, interfacing**
   EMDN : **Z120400199 – General Medicine Diagnosis and Monitoring instruments-Other**

2. Name and address of the manufacturer: / *Ime in naslov proizvajalca:*

BIOCORP PRODUCTION
ZI de Lavaur – La Béchade
63500 ISSOIRE, France
SRN : FR-MF-000011122

3. This declaration of conformity is issued under the sole responsibility of the manufacturer. / *Ta izjava o skladnosti je izdana na izključno odgovornost proizvajalca.*

4. Object of the declaration: / *Predmet izjava:*

See table in appendix: Product(s) identification / *Glej tabelo v dodatku: identifikacije pripomočka.*

5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: / *Predmet zgoraj opisane izjava je v skladu z ustrezno usklajevalno zakonodajo Unije:*

The products(s) listed in appendix, covered by the present declaration, is(are) in conformity with

- **REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC Annex IV**
- **DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC**
- **DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility**
- **DIRECTIVE 2014/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits**
- **DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment**

Proizvodi, navedeni v dodatku, ki jih zajema ta izjava, so v skladu z

- ***UREDBA (EU) 2017/745 EVROPSKEGA PARLAMENTA IN SVETA z dne 5. aprila 2017 o medicinskih pripomočkih, spremembi Direktive 2001/83/ES, Uredbe (ES) št. 178/2002 in Uredbe (ES) št. 1223/2009 ter razveljavitvi direktiv Sveta 90/385/EGS in 93/42/EGS Priloga IV***
- ***DIREKTIVA 2014/53/EU EVROPSKEGA PARLAMENTA IN SVETA z dne 16. aprila 2014 o harmonizaciji zakonodaj držav članic y zvezi z dostopnostjo radijske opreme na trgu in razvelja-vitvi Direktive 1999/5/ES***
- ***DIREKTIVA 2014/30/EU EVROPSKEGA PARLAMENTA IN SVETA z dne 26. februarja 2014 o harmonizaciji zakonodaj držav članic v zvezi z elektromagnetno združljivostjo***

- ***DIREKTIVA 2014/35/EU EVROPSKEGA PARLAMENTA IN SVETA z dne 26. februarja 2014 o harmonizaciji zakonodaj držav članic v zvezi z omogočanjem dostopnosti na trgu električne opreme, ki je načrtovana za uporabo znotraj določenih napetostnih mej***
- ***DIREKTIVA 2011/65/EU EVROPSKEGA PARLAMENTA IN SVETA z dne 8. junija 2011 o omejevanju uporabe nekaterih nevarnih snovi v električni in elektronski opremi***

6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared: */ Sklicevanja na uporabljene ustrezne harmonizirane standarde ali sklicevanja na druge tehnične specifikacije, v zvezi s katerimi se izjavlja skladnost:*

- **2017/745/EU : The General Safety and Performance Requirements (GSPR) for the medical device(s) in appendix are assessed by the following standards / Splošnimi zahteve glede varnosti in učinkovitosti (GSPR) za medicinski(-e) pripomoček(-e) iz dodatka so ocenjeni z naslednjimi standardi:**
  EN ISO 13485:2016/A11:2021 ; EN ISO 14971:2019/A11:2021 ; EN ISO 15223-1:2021 ; ISO 10993-1:2018 ; IEC 62366-1:2015/A1:2020 ; IEC 60601-1-2:2014 Ed4.0;
- **2014/53/EU : The Essential Requirements for the product(s) in appendix are assessed by the following standards and regulations / Bistvene zahteve za izdelek(-e) v dodatku so ocenjeni z naslednjimi standardi in predpisi:**
  - **ETSI EN 300 328 V2.2.2 ;**
  - **2014/30/EU : ETSI EN 301 489-1 V1.9.2 ; EN 55035:2017/A11:2020**
  - **2014/35/EU : CEN EN 62311:2008 ; EN 62368-1:2014/AC:2015 ; CEN EN 61010-1:2010/A1:2019**
- **2011/65/EU : The obligations for the product(s) in appendix are assessed by the following standards and regulations / Obveznosti za izdelek(-e) v dodatku so ocenjene z naslednjimi standardi in predpisi:**
- **IEC 63000:2016/A1:2022**

7. The following notified body is involved in the certification process: / V postopek certificiranja je vključen naslednji priglašeni organ:

Certified by manufacturer / Potrjeno s strani proizvajalec

8. Where applicable, description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity: / Po potrebi opis dodatne opreme in sestavnih delov, vključno s programsko opremo, ki omogočajo, da radijska oprema deluje, kot je predvideno in zajeto v izjava EU o skladnosti:

Not applicable / Se ne uporablja

9. Additional information: / *Dodatne informacije:*

Signed for and on behalf of: / *Podpisano za in v imenu:* **BIOCORP PRODUCTION**
Place and date of issue: / *Kraj in datum izdaje:* **Issoire, 19/02/2025**
Name, function & signature: / *Ime, funkcija in podpis:* **Alexia GARIN, QARA Director**

Valid starting with the above date until product change or five years.
Velja od zgoraj navedenega datuma do spremembe izdelka ali pet let.

Appendix: Product(s) identification: / *Dodatek: Identifikacija izdelka(-ov):*

Product(s) Name (Countries bigram) / *Ime izdelka (izdelkov) (Države bigram)*	Model(s) / *Model(i)*	Reference(s)/ *Referenca(-e)*	Product(s) UDI-DI / *Izdelek(-i) UDI-DI* (GTIN)	Class (Rule(s)) / *Razred (Pravilo(-a))*	Picture(s) / *Slika(e)*
MALLYA G SVN	EFA2	0174534	03701409145343	Class I (rule 13)