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 v1.0**
   GMDN: **36862 : Patient monitoring system module, interfacing**
   EMDN: **Z12040199 - 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

- **The Medical Device Regulation (MDR) 2017/745/EU Annex IV**
- **The Radio Equipment Directive (RED) 2014/53/EU**
- **The Electromagnetic compatibility directive (EMC) 2014/30/EU**
- **The Low Voltage Directive (LVD) 2014/35/EU**
- **The Restriction of Hazardous Substances directive (RoHS) 2011/65/EU**

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

- ***Förordningen om medicintekniska produkter 2017/745/EU Priloge IV***
- ***RED-direktivet 2014/53/EU***
- ***Direktivet om elektromagnetisk kompatibilitet 2014/30/EU.***
- ***Direktivet om lågspänning 2014/35/EU***
- ***RoHS-direktivet 2011/65/EU***

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, 29/11/2024**
Name, function & signature: / *Ime, funkcija in podpis:* **Alexia GARIN, VP QARA**

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)