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Crevacuore, October 18th, 2021

Subject: Medical Devices REDICUFF size 5cm x6 meters, 7,5cm x6 meters and 10cm x6 meters.

Declaration of conformity for the above mentioned Medical Devices, produced by Yanga S.r.l., to the quality essential requirements of MDR 745/2017.

The undersigned firm YANGA S.r.l., located in Crevacuore (BI), via Monte Orfano 21, manufacturer of the above mentioned Medical Device

DECLARES

under its responsibility that these devices satisfy all the applicable dispositions of Directive MDR 745/2017 for Medical Devices.

Thus, YANGA S.r.I. guarantees and declares under its responsibility what follows:

- the above mentioned Medical Devices satisfy all the applicable dispositions of Directive MDR 45/2017;
- the above mentioned Medical Devices are not sold in sterile packaging;
- the above mentioned Medical Devices are not to be intended as measurement instruments;
- the above mentioned Medical Devices are not to be used for clinical trials.

The undersigned YANGA S.r.l. commits to put at disposition of competent Authority the technical documentation, specified in the MDR 745/2017 Directive for a period of five years starting from the last manufacturing date of the product.

It is hereby declared that the above mentioned Medical Devices are in conformity with what is prescribed in the Directive MDR 745/2017, and they will be put on the market with CE marking, following the dispositions of such Directive.

NON STERILE – CLASS I DEVICE

Please find hereafter the BASIC UDI-DI for the above mentioned products.

CUFF P 5: 001 - 3395429 13001 CM CUFF P 7,5: 002 - 3395429 13002 CP CUFF P 10: 003 - 3395429 13003 CR

CUFF N 5: 101 - 3395429 13101 CS CUFF N 7,5: 102 - 3395429 13102 CU CUFF N 10: 103 - 3395429 13103 CW

dr. Vittorio Bobba Managing Director

Vitrio

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