S.I.I.T. S.r.l. UNIPERSONALE

Innovative Healthcare Products Contract Development & Manufacturing

DECLARATION OF CONFORMITY CE

The company S.I.I.T srl, located at Trezzano sul Naviglio, via Ariosto 50/60, as Manufacturer of the Medical device

Fluxan

declares under its own responsibility that the Medical device object of this declaration satisfies the dispositions of Law Decree 24 February 1997, N° 46, (Directive 93/42/CEE on Medical devices) and subsequent amendments and additions (Implementation of Directive 93/42/EEC and subsequent amendments concerning the CE marking Medical Devices)

We declare that:

- The Medical device satisfies the requisites specified in Enclose I of Law Decree 24 February 1997, N° 46
- The Medical device is classified as **Class IIa, invasive in natural orifice, of short-term use**, following criteria of classification specified in Enclose IX, rule 5 - Law Decree 24 February 1997, N° 46
- Destination of use is **prevention and treatment of symptoms associated to reducing gastroesophageal reflux disease**
- The Medical device is commercialized in **NON STERILE packaging**
- The Medical device is **NOT MEASURE DEVICE**
- The Medical device is not to be used for **CLINICAL INVESTIGATIONS**
- The Medical device is commercialized with the mark CE as specified in art. 16 of Law Decree 24 February 1997, N° 46 and is manufactured according to the Quality Management System that meets the requirements of Annex V and VII to Directive 93/42/EEC and subsequent amendments, in accordance with a certificate issued by ITALCERT (ON 0426) in force at the date of this declaration

Trezzano s/N (MI), 18/01/2021

CEO

Dr. Andrea Domizio Costa

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