

Lucca, 08/09/2022

## EU DECLARATION OF CONFORMITY

Mr. Andrea Bernacchi, as C.E.O. of INDUSTRIE CELTEX S.p.A., with registered office in Via Traversa del Marginone, 23- 55015 Montecarlo (LU), **SRN: IT-MF-000027968**, manufacturer of the Medical Device "LENZUOLINO MEDICO" (Disposable medical roll), **Basic UDI-DI: 8022650C60000ZN**, in the variant:

**62655 – Medilux Five**

**62657 – Medilux Six**

meant to be used to protect beds, stretchers, chairs or similar equipment during their use for medical activities,

### DECLARES

Under its own responsibility, that the Medical Device referred to in object meets all the general requirements on safety and performance, applicable, of Annex I of Regulation EU 745/2017 on Medical Devices.

To this end, the company as represented above, warrants and declares the following:

- that the device in object complies with the applicable provisions of Regulation EU 2017/745 of European parliament and council;
- that the Device in object is sold in a NON STERILE form;
- that the Device in object belongs to Class I according to Regulation EU 745/2017, being a non-invasive device according to Rule 1 and not being applicable the other rules defined in ANNEX VIII, Chapter III, of that Regulation;
- that the Device complies with the general requirements on safety and performance and provisions of Regulation EU 745/2017 as per the current version of the Technical File;
- that the Device is manufactured in accordance with the Quality System that meets the requirements of Annex IX of the above mentioned Regulation.

The manufacturer also declares:

- to have established and maintain an appropriate procedure to ensure the after-sales surveillance required by Regulations EU 745/2017;
- to keep the technical documentation relating to the Medical Device at the disposal of the competent Authorities at their premises.

### Applicable harmonized European standards

The list is provided in the relevant technical file Annex 4 to section 1.



**INDUSTRIE CELTEX**®

**INSTRUCTIONS FOR USE**

Product meant to cover the examination couch or other dry surface where the patient may lie during a medical examination or outpatient treatment.

Ensures patient's contact with a clean, non-irritating surface and avoids the need for frequent equipment cleaning procedures.

Do not use in contact with exposed wounds or injured skin. Do not use in a sterile environment (clean room); contact with sterile equipment does not guarantee that the equipment remains sterile.

**Do not reuse.** In case of accidental contact with potentially harmful fluids, dispose it properly. The medical device is not sterile.

No sterilization or cleaning is provided for the medical device by the user.

**The device is for single use only after which it has to be disposed according to local regulations.** This medical device does not contain any toxic or dangerous materials.

INDUSTRIE CELTEX SPA  
C.E.O.

Andrea Bernacchi