LENZUOLINO

MEDILUX XL -MEDICAL ROLL MT 150 H 59 1X4

COUCH ROLLS

C61259

Technical Details

Raw Material	*100% PURE CELLULOSE*	Absorption by immers.%(+/- 10)	*480*	Nr.Sheets	*395*
Nr.Plies	*2*	Absorption Klemm mm/10(+/-5)	*100*	Roll Length (mt)	*150,00*
Grammage per Ply (gr/mq)	*17,0*	Longit.Dry Tract. Res. N/m(+/-50)	*470*	Roll Diameter	*16,00*
Colour	*WHITE*	Transv.Dry Tract. Res.N/m(+/-50)	*235*	Core	*RIGID*
Whiteness Point	*85*	Longit.Wet Tract. Res.N/m(+/-50)	*164*	Core Diameter (mm)	*39*
Whitening Method	*ECF*	Transv.Wet Tract. Res.N/m(+/-50)	*82*	Rolls per Pack	*1*
WS Treatment	*YES*	Sheet Height (cm)	*59,50*	Packs per Carton	*4*
Embossing	*MICRO EMBOSSED*	Sheet Length (cm)	*38,00*	EAN Pack	*8022650612596*
Ply Bond veli	*PUNTA PUNTA SYSTEM*	Perforation	*YES*	EAN Carton	*18022650612593*

Logistic Details

Pack Dimensions (cm HxLxD)	- -	Packaging Material	*POLYETHYLENE*	Cartons per Pallet	*36*
Carton Dimensions (cm HxLxD)	*60,10x32,00x32,00*	Carton Material	*CARTON*	Cartons per Layer	*9*
Pallet Dimensions (cm HxLxD)	*255,40x120,00x96,00*	Pallet Certification	*EPAL*	Layers per pallet	*4*
Carton Volume (mc)	*0,0615*	Pallet Construction	- -	Demipallet	*NO*

This product meets EU GPP criteria, therefore it can be offered in public tenders organized by contracting authorities.

The tecnical data indicated above is generated by testing performed on articles belonging to our standard spectrum and are provided only for informational purposes.Additional information may bey supplied upon request.All dimensions are subject to tolerance as by law enacted.

INDUSTRIE CELTEX

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www.industrieceltex.com

Montecarlo, 08/03/2024

DECLARATION OF CONFORMITY CE

Mr. Andrea Bernacchi, as C.E.O. of INDUSTRIE CELTEX S.p.A., with registered office in Via Traversa del del Marginone, 21/23- 55015 Montecarlo (LU), ***SRN: IT-MF-000027968,*** manufacturer of the Medical Device "LENZUOLINO MEDICO" (Disposable medical roll), ***Basic UDI-DI: 8022650C60000ZN,*** in the variant:

C61259 MEDILUX XL -MEDICAL ROLL MT 150 H 59 1X4

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 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 harmonised European standards

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

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 S.p.A.
C.E.O.
Andrea Bernacchi

Montecarlo, 08/03/2024

DECLARATION OF CONFORMITY
DERMATOLOGICALLY TESTED

We hereby declare that the following product:

C61259 MEDILUX XL -MEDICAL ROLL MT 150 H 59 1X4

passed a dermatological test on humans. The supervision of these tests and the evaluations were carried out by medical staff.

No toxic/irritative intolerance reactions carried out in the test and therefore the material type can be declared as dermatologically tested.

INDUSTRIE CELTEX S.p.A.
Quality Office Manager
Alessandro Caprilli Carrara

Montecarlo, 08/03/2024

EU ECOLABEL DECLARATION

We hereby declare that the following product:

C61259 MEDILUX XL -MEDICAL ROLL MT 150 H 59 1X4

complies with EU ECOLABEL certification.
Additionally, we will inform you if any changes regarding the above take place.

License EU ECOLABEL: IT/004/010

INDUSTRIE CELTEX S.p.A.
Quality Office Manager
Alessandro Caprilli Carrara

Montecarlo, 08/03/2024

PEFC DECLARATION

We hereby declare that the following product:

C61259 MEDILUX XL -MEDICAL ROLL MT 150 H 59 1X4

is certified as PEFC product.
Additionally, we will inform you if any changes regarding the above take place.

Logo-License PEFC: PEFC/18-32-24

INDUSTRIE CELTEX S.p.A.
PEFC Responsible
Alessandro Caprilli Carrara