

Manufacturer and Plant	Alle S.r.l. Via XX settembre, 74 - 46019 Viadana (MN) Tel.: + 39 0445 329811 - Fax.: + 39 0445 865246
Medical Device Type	NON INVASIVE, INACTIVE, DISPOSABLE, STERILE
Product Category(ies)	Sterile medical devices for operating theatre equipment: drapes, non woven custom kits, cuffs and sheets to cover equipment
Classification	Class Is - rule n. 1 of the Annex IX MDD 93/42EC and its updates
Procedure to the CE Certificate	According to Annex V of the Directive 93/42EC and its updates
CE CERTIFICATE	G2S 098477 0003 Rev. 01 date: 2020/02/17 valid until: 2024/05/26
Notified Body ID n.	0123 ; TUV SUD Product Service GmbH Zertifierstelle–Ridlerstrasse 65, 80339 Munchen - Germany

The manufacturer **Alle S.r.l.** declares, under its own responsibility, that the product listed below meets the requirements of the Directive 93/42/EEC, incorporated in Italy with italian legislative decree 46 of february 24, 1997 and subsequent updates and amended by the directive 2007/47/EC and also declares that the same device has been manufactured according to the applicable harmonized standard EN ISO 13485:2016.

Code	Description
270101	Patient set
270102	Operator set
270103	Assistant set
270105	Implantology set
270106	Base set
270107	Preparation set
270108	Three drapes set
270405	Surgical gown in blue sms microfibre
270406	Surgical gown in blue sms microfibre
270407	Surgical gown in blue sms microfibre
270408	Surgical gown in Dupont™ Softesse®
270409	Surgical gown in Dupont™ Softesse®
270410	Surgical gown in Dupont™ Softesse®
270213	Waterproof mayo cover
270214	Waterproof table cover drape
270218	Standard drape
270219	Standard drape
270220	Standard drape
270221	Standard drape
270201	Twolayers utility drape absorbent + waterproof
270202	Twolayers utility drape absorbent + waterproof
270203	Twolayers utility drape absorbent + waterproof
270204	Twolayers utility drape absorbent + waterproof
270205	Twolayers utility drape absorbent + waterproof
270206	Twolayers utility drape absorbent + waterproof with adhesive band
270207	Twolayers utility drape absorbent + waterproof with adhesive band
270208	Twolayers utility drape absorbent + waterproof with adhesive band
270215	Twolayers utility drape absorbent + waterproof with adhesive hole 6x9 cm

270216	Twolayers utility drape absorbent + waterproof with adhesive hole 6x9 cm
270217	Twolayers utility drape absorbent + waterproof with adhesive hole 6x9 cm
270228	Twolayers utility drape absorbent + waterproof with adhesive hole 6x9 cm
270209	Twolayers utility drape absorbent + waterproof with "u" hole 11x30 cm
270210	Twolayers utility drape absorbent + waterproof with adhesive "u" hole 11x9 cm
270211	Twolayers utility drape absorbent + waterproof with adhesive "u" hole 11x9 cm
270212	Twolayers utility drape absorbent + waterproof with adhesive "u" hole 6.5x30 cm
270222	Drape in Dupont™ Softesse®
270223	Drape in Dupont™ Softesse® with "u" hole 6.5 x 50 cm and tube holder
270224	Drape in Dupont™ Softesse® with "u" hole 6.5 x 50 cm and tube holder
270225	Drape in Dupont™ Softesse® with adhesive hole 6 x 9
270226	No panic drape with transparent pe visual rectangular hole, triangular hole and tube holder
270310	Waterproof cover sheat with inserter
270302	Cover sheath with 2 blue adhesives
270303	Cover sheath with 2 blue adhesives
270301	5 blue pvc adhesive films inside 1 envelope
270227	Transparent pvc drape with adhesive band 4x40 cm
270702	Sterile dry paper towel cm. 30x40
270304	Cover sheat with 2 white adhesives
270305	Cover sheat with 2 white adhesives
270110	Special set for Internacional Crown
270114	Special set for Dr. Gallo
270119	Special set for Plenido Dental Manresa
270120	Special set for C D Unamunzaga – Etxebarria
270121	Special set for Lorente Alvarez- Beigbeder
270122	Special set Euronda Alle
270123	Surgery kit
270427	Green spunbond surgical gown with cuffs
270428	Blue spunbond surgical gown with cuffs
270315	Kit two medical adhesive
270316	Transparent cover sheath with elastic
270230	Twolayers utility drape absorbent + waterproof with "u" hole 15x25 cm and adhesive 6x6 cm
270306	Cover sheath with elastic
270307	Cover sheath with elastic
270126	Doctor set
270127	Pure implant kit
270118	Set especial clinica velez
270128	Standard implantology kit
270810	Adesivos esteriles

APPLICABLE STANDARDS

General Standards and Technical Standards are listed in Annex n.8 Technical File FT03

VALIDITY

This declaration of conformity is valid until 2024/05/26.

Viadana, **2021/10/25**

Nicola Basso
Deputy CEO

