

DoC Procedure Packs - Refills

Sted og prosess NP Vennesla / TEKNISK FIL / Procedure
Packs / 6.5 Innholdsposter/Refills
Sist godkjent dato 06.09.2023 (Kristin Sannes)

Dokumentkategori
Neste revisjonsdato
Dokumentansvarlig Kristin Sannes

STATEMENT PROCEDURE PACKS

REGULATION ON MEDICAL DEVICES (EU) MDD 93/42/EEC

NORGESPLASTER AS**SRN:** NO-MF-000022061

This statement is issued by Norgesplaster AS in accordance with MDD (Medical Device Directive) 93/42/EEC and with Article 22 of the Regulation on Medical Devices (EU) 2017/745.

Norgesplaster AS has combined devices bearing a CE marking with other devices or products accorded MDD/MDR in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a procedure pack.

Norgesplaster AS hereby declares that:

- we have verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and have carried out the activities in accordance with those instructions,
- we have packaged the procedure packs and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together,
- the activity of combining devices and, if applicable, other products as a procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

Basic UDI-DI: 7022750061005Y

EMDN (CND): V0501

GMDN: 43000

Medical purpose: Assortments of products to be used in First Aid situations, packed in mobile kits.

List of procedure packs on following page(s).

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Sist godkjent dato	06.09.2023 (Kristin Sannes)	Neste revisjonsdato	
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REF	Name of Procedure Pack		Highest risk class
Refills			
24591	Snøgg	Innholdspose 1. Plaster	MDR, Class I
24592	Snøgg	Innholdspose 2. Brudd og klemskader	MDD, Class 2a
24593	Snøgg	Innholdspose 3. Sår og Kutt	MDD, Class Is
24594	Snøgg	Innholdspose 4. Hygiene	MDR, Class I
24595	Snøgg	Innholdspose 5. Øyeskylle	MDD, Class Is
24596	Snøgg	Innholdspose 6. Blødninger	MDD, Class Is
24597	Snøgg	Innholdspose 7. Brannskade	MDD, Class 2b
24598	Snøgg	Innholdspose 8. Redningspakke	MDR, Class I
24599	Snøgg	Innholdspose 9. Store blødninger	MDD, Class Is
24532	Snøgg	Innholdspose 1. Plaster Blue	MDR, Class I
24535	Snøgg	Innholdspose 7. Brannskade Blue	MDD, Class 2b
24531	Snøgg	Innhold bårerepute	MDD, Class Is
24503	Snøgg	Innhold Flexi Håndverker	MDD, Class 2b
24505	Snøgg	Refill Medisinskap/Koffert	MDD, Class 2b
24517	Snøgg	Refill Flexi	MDD, Class 2b
24525	Snøgg	Innhold Snøggkofferten Multi	MDD, Class 2b
24529	Snøgg	Refill forbruksmateriell	MDD, Class Is
24533	Snøgg	Innhold Mannskapsveske	MDD, Class Is
4398	Norgesplaster	Kvikk Sårpakke	MDR, Class I

Vennesla,



Kristin Sannes

Regulatory Affairs and Quality Manager
 Person Responsible for Regulatory Compliance,
 Norgesplaster AS