

EC-Declaration of conformity

Manufacturer: Vogt Medical Vertrieb GmbH
Address: Rüppurrer Str. 1A, Haus B, 76137 Karlsruhe, Germany
Product: **Surgical clothes, non-sterile, for single use**
see annex
Classification: Class I

We declare on our own responsibility that the medical devices specified above, complies with the relevant Essential Requirement of the Directive 93/42/EEC, taking in the account the state of art.

This declaration concerns all denoted medical devices until the date **2023-10-31**.

The manufacturer is solely responsible for issuance of the declaration of conformity.

Place, Data of Issue: Karlsruhe, 2020-09-15

Signature:

Michael Vogt, Managing Director
(Name, Function)



Filename with revision :
DoC_VM_Surgical clothes non
sterile
Rev. 5

Created by :
ob

Created at :
14.02.12

Modified by :
ak

Modified at :
17.09.20

Annex to EC-Declaration of conformity

Catalog No.	Product
1314312	VM Surgical Mask, with stitched ties, non-sterile, size 17.5 x 9.5cm, PP nonwoven 3ply (17g spunbond+ 20gmeltblown + 24 g spunbond), blue
1314313	VM Surgical Mask, with two soft elasticated loops for fixing behind ears, non-sterile, 17.5 x 9.5cm, PP nonwoven 3ply (17g spunbond+ 20gmeltblown + 24 g spunbond), blue
1314313C	VM Surgical Mask, with two soft elasticated loops for fixing behind ears, non-sterile, 17.5 x 9.5cm, 3ply (23gsm spunbond+ 25gsm meltblown + 25gsm spunbond), blue
1314313TKC	VM Surgical Mask, with two soft elasticated loops for fixing behind ears, non-sterile, 17.5 x 9.5cm, 3ply (23gsm spunbond+ 25gsm meltblown + 25gsm spunbond), blue
1314313JJC	VM Surgical Mask, with two soft elasticated loops for fixing behind ears, non-sterile, 17.5 x 9.5cm, 3ply (23gsm spunbond+ 25gsm meltblown + 25gsm spunbond), blue
1314314	VM Surgical Mask, Anti-fogging, one sizes, non-sterile, for wearers of glasses; with anti-fog band on the nose to help prevent the eyeglasses from fogging, blue
1314315	VM Surgical Cap, Bouffant Cap, all-round beret-shaped cap with an elastic rim, non-sterile, one size, spunbond 25 gsm, blue
1314315XX	VM Surgical Cap, Bouffant Cap, non-sterile, all-round beret-shaped cap with an elastic rim, one size, spunbond 10 gsm, blue
1314316	VM Surgical Cap, Helmet-shaped, for full protection with long chin bands; save cover of the whole head and neck area, non-sterile, 54x34cm, spunbond 20 gsm, blue
1314317	VM Surgical Cap, Basic, non-sterile, one size, round shape, with doubly reinforced sides, SMS 35 gsm, blue
1314318	VM Surgical Cap, Standard, non-sterile, one size, fully formed neck section with an elastic rim, SMS 35 gsm, blue
1314319	VM Surgical Shoe Covers, non-sterile, one size, with an elastic rim, PE 4 g, blue
1314319XX	VM Surgical Shoe Covers, non-sterile, size 15 x 39 cm, with an elastic rim, PE 3 g, blue
1314510	VM Isolation Gown for visitor, non-sterile, length 115 cm, width 140 cm, with tie on neck and waist, with knit cuffs, spunbond 30gsm, green
1314511	VM Surgical Clothes Set non-sterile: Surgical Gown Special, XL, length 130cm width 150cm, wraparound, with additional impermeable layer in the chest and extra-overlapping at the back, 45gsm Standard SMS, blue, 2 hand wipes 38cm*48cm, 50gsm Tissue, white
1314512	VM Surgical Clothes Set non-sterile: Surgical Gown Special, L, length 120cm width 140 cm, wraparound, with additional impermeable layer in the chest and extra-overlapping at the back, 45gsm Standard SMS, blue, 2 hand wipes 38cm*48cm, 50gsm Tissue, white
1314513	VM Surgical Clothes Set non-sterile: Surgical Gown Special, M, length 115cm width 137 cm, wraparound, with additional impermeable layer in the chest and extra-overlapping at the back, 45gsm Standard SMS, blue, 2 hand wipes 38cm*48cm, 50gsm Tissue, white
1314514	VM Isolation gown for visitors non-sterile, length 115cm width 140cm, with tie on neck & waist, with elastic cuff, spunbond 30gsm, blue
1314514/20	VM Isolation gown for visitors non-sterile, length 115cm width 137cm, with tie on neck & waist with elastic cuff, spunbond 20gsm, blue
1314515	VM Surgical Clothes Set non-sterile: Surgical Gown Special, M, length 115cm width 137 cm, wraparound, with additional impermeable layer in the chest and extra-overlapping at the back, 45gsm Standard SMS, blue, 2 hand wipes 38cm*48cm, 50gsm Tissue, SMS wrapping, white
1314516	VM Surgical Clothes Set non-sterile: Surgical Gown Special, L, length 120cm width 140 cm, wraparound, with additional impermeable layer in the chest and extra-overlapping at the back, 45gsm Standard SMS, blue, 2 hand wipes 38cm*48cm, 50gsm Tissue, SMS wrapping, white
1314517	VM Surgical Clothes Set non-sterile: Surgical Gown Special, XL, length 130cm width 150cm, wraparound, with additional impermeable layer in the chest and extra-overlapping at the back, 45gsm Standard SMS, blue, 2 hand wipes 38cm*48cm, 50gsm Tissue, SMS wrapping, white
1314518	VM Isolation Gown for visitor, non-sterile, length 120 cm, width 134 cm, with tie on neck and waist, with knit cuffs, Spunbond 18gsm+11 PE, green

Place, Date of Issue: Karlsruhe, 2020-09-12

Signature:

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