

VšĮ Klaipėdos universitetinė ligoninė

2016-04-12 Nr. KD16-67

Į 2016-03-31 Nr. 1186

PASIŪLYMAS

Atsakydami į kvietimą dalyvauti supaprastintame švino apsauginių drabužių pirkime apklausos būdu, siūlome Vokietijos gamintojo „Medical Index GmbH“ gaminamus apsauginius švino drabužius.

Eil. Nr.	Parametrai	Parametro reikšmė	Kiekis, vnt.	Atitikimas	Vnt. kaina Eur su PVM	Viso kaina Eur su PVM
	2 jų dalių individualios personalo rentgeno apsaugos					
1	Skydliaukės apsauga	Su praplatinta priekine dalimi 0,50 mmPb	5	0,50 mmPb	78,65	393,25
2	Vienpusė prijuostė personalui	0,50 mmPb priekis 0,25 mmPb nugara 60x110 cm Pageidautina mėlyna spalva	5	0,50 mmPb priekis 0,25 mmPb nugara 60x110 cm Mėlyna spalva	326,70	1633,50
	Individualioms apsaugos priemonės nuo jonizuojančios spinduliuotės					
1	Paskirtis	Apsauga nuo jonizuojančios spinduliuotės (Tc99m, vidutinė energija 140 kv)		Drabužiai pagaminti pagal IEC 1331-1 ir IEC 61331-3 standartus, kuriuose numatytas testavimas esant 100 kV volтажui su 0,2 mm vario filtracija.		
2	Apsaugos priemonė skydliaukei	Ne mažiau 0,5 mmPb ekvivalento, dydis M	3		78,65	235,95
3	Apsaugos priemonė kūnui		2		677,60	1355,20
3.1	Sarafano tipo, Pb ekvivalento apsauga priekyje ne mažiau 0,5 mm ir ne mažiau 0,25 mm nugaroje			Sarafano tipo, Pb priekyje 0,5 mm ir 0,25 mm nugaroje		
3.2	Dydis M, ilgis 90 cm			Dydis M		
3.3	Sarafanas turi būti lengvai užsegamas lipnia juosta ant peties ir šono srityje ir papildomai fiksuojamas diržu liemens srityje			Sarafanas lengvai užsegamas lipnia juosta ant peties ir šono srityje ir papildomai fiksuojamas diržu liemens srityje		
3.4	Reikalingos 2 kišenės (viena krūtinės srityje, kita klubo srityje)			2 kišenės (viena krūtinės srityje, kita klubo srityje)		
4.	Apsaugos priemonių spalva – mėlyna			Mėlyna		
5	Apsaugos priemonė turi būti atspari sulenkimams, lengvai valomu paviršiumi (vanduo,			Apsaugos priemonė atspari sulenkimams, lengvai valomu		

	muilas, dezinfekuojančios medžiagos, spiritas 70 laipsnių)			paviršiumi (vanduo, muilas, dezinfekuojančios medžiagos, spiritas 70 laipsnių) MATRIX audinys		
6	Gamintojo nustatyta apsauginės priemonės naudojimo trukmė			Nuo 5 iki 10 metų		
7	CE sertifikatas			Pateikiamas		
8	Gamintojas, jo duomenys, atitikties sertifikatai			Medical Index GmbH ISO 9001, ISO 13485		
9	Asmeninės apsaugos priemonės bandymų protokolai			Pateikiami kartu su prekėmis		
10	Instrukcija lietuvių kalba			Pateikiama		
11	Garantinis laikotarpis	Ne mažiau 5 metai		5 metai		
12	Viso pasiūlymo kaina Eur su PVM					3617,90

Švino apsauginė apykaklė



Vienpusė prijuostė personalui



Sarafano tipo prijuostė



Administratorė – vadybininkė

Jovita Morkevičienė

EG-Baumusterprüfbescheinigung

Nr. P5 04 06 50477 001



Zertifikatsinhaber: medical index GmbH

Mayerhof 5
74906 Bad Rappenau
Deutschland

Produkt: PSA zum Schutz gegen ionisierende Strahlung
Röntgenschutzartikel für den
Strahlenanwender

Diese EG-Baumusterprüfbescheinigung bestätigt die Übereinstimmung des bezeichneten Produktes mit den grundlegenden Anforderungen gemäß Artikel 8, Absatz 4 (Geräte der Kategorie 3) der Richtlinie des Rates Nr. 89/686/EWG für persönliche Schutzausrüstungen. Prüfgrundlage ist ausschließlich das zur Prüfung und Zertifizierung vorgestellte Prüfmuster sowie dessen technische Dokumentation. Umseitige Hinweise sind zu beachten.

Prüfbericht Nr: 70049739



Datum, 2004-06-25

TÜV PRODUCT SERVICE GMBH ist gemeldete Stelle gemäß der Richtlinie des Rates Nr. 89/686/EWG für persönliche Schutzausrüstungen, notifiziert durch Veröffentlichung im Amtsblatt der EG Nr. C 203/44 vom 22.7.1994 mit der Kennnummer 0123.

Seite 1 von 2

TÜV PRODUCT SERVICE GMBH • Zertifizierstelle • Ridlerstrasse 65 • D-80339 München
Gruppe TÜV Süddeutschland

Ženklas: TUV Product Service

EB tipo patikros sertifikatas
Nr. P 5 04 06 50477 001

Sertifikato savininkas: „medical index GmbH“

Meyerhof 5
74906 Bad Rappenau
Vokietija

Produktas: Asmeninės apsaugos įranga apsaugai nuo jonizuojančiosios spinduliuotės
gaminys apsaugai nuo rentgeno spindulių, skirtas dirbantiems su rentgeno ir panašiais aparatais

Šis EB tipo patikros sertifikatas patvirtina, kad nurodytas produktas atitinka esminius reikalavimus pagal Tarybos direktyvos nr. 89/686/EEB asmeninėms apsaugos priemonėms 8 straipsnio, 4 pastraipą (3 kategorijos prietaisai). Patikros pagrindas yra tik patikrai ir sertifikavimui pateiktas pavyzdys bei jo techninė dokumentacija. Prašome atkreipti dėmesį į informaciją kitoje lapo pusėje.

Patikros protokolo nr.: 70049739

Ženklas: TUV. 180354.

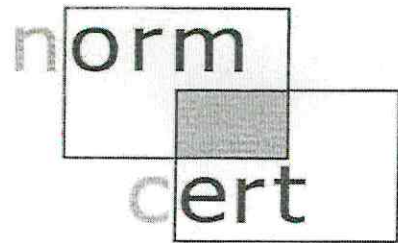
Data: 2004 06 25

/parašas/

„TUV PRODUCT SERVICE GMBH“ yra registruota tarnyba pagal Tarybos direktyvą nr. 89/686/EEB asmeninėms apsaugos priemonėms, paskirtoji oficialiu paskelbimu 1994 07 22 EB „Oficialiame leidinyje“ nr. C 203/44 numeriu 0123.

p. 1 / 2

„TUV PRODUCT SERVICE GMBH“ sertifikavimo tarnyba, Ridlerstrasse 65, D-80339
Miunchenas
Grupė „TUV Pietų Vokietija“



Hiermit wird bescheinigt, dass das Unternehmen

medical index GmbH
Mayerhof 5
D-74906 Bad Rappenau

ein **Qualitätsmanagementsystem** entsprechend der unten
genannten DIN EN ISO-Norm eingeführt hat und wirksam anwendet.

Geltungsbereich:

Herstellung und Handel von medizintechnischen Produkten

Der Nachweis, dass das Managementsystem die Forderungen des
folgenden Regelwerks erfüllt, wurde im Rahmen des Audits mit dem
Bericht Q201-2306 erbracht:

DIN EN ISO 9001

Die Zertifizierung bzw. das Zertifikat hat eine Gültigkeit von 3 Jahren,
sofern die jährlichen Überwachungsaudits in den festgelegten Fristen
mit positivem Ergebnis abgeschlossen werden.

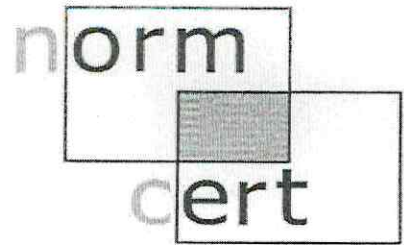
Zertifikatsnummer 2301318
Ausstellungsdatum 27.06.2015
Zertifikat gültig bis 25.06.2018

norm-cert

Anja Steidl
Anja Steidl
Zertifizierungsstellenleitung



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Hiermit wird bescheinigt, dass das Unternehmen

medical index GmbH
Mayerhof 5
D-74906 Bad Rappenau

ein **Qualitätsmanagementsystem** entsprechend der unten
genannten DIN EN ISO-Norm eingeführt hat und wirksam anwendet.

Geltungsbereich:

Herstellung und Handel von medizintechnischen Produkten

Der Nachweis, dass das Managementsystem die Forderungen des
folgenden Regelwerks erfüllt, wurde im Rahmen des Audits mit dem
Bericht Q201-2306 erbracht:

DIN EN ISO 13485

Die Zertifizierung bzw. das Zertifikat hat eine Gültigkeit von 3 Jahren,
sofern die jährlichen Überwachungsaudits in den festgelegten Fristen
mit positivem Ergebnis abgeschlossen werden.

Zertifikatsnummer 2301320
Ausstellungsdatum 27.06.2015
Zertifikat gültig bis 25.06.2018

norm-cert


Anja Steidl
Zertifizierungsstellenleitung



norm-cert / Eberhard-Finckh-Straße 26 / 72829 Engstingen

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Medical Index GmbH

Gesellschaft für medizin-technische Produkte

Instructions of use

X-Ray Protective Equipment

We thank you for using Medical Index equipment. Before using it, we recommend you to examine the following instructions with a strong attention:

If you desire any further information concerning the Medical Index radiation protective clothing, please do not hesitate to contact us.

Caution

The equipment are personal protective equipment against X-rays exposure caused by x-rays generating tubes used in radiology and are intended to reduce the x-ray exposure of the wearer.

As personal protective equipment, their choice and use has to conform to the european council directive no. 89/656/EEC of 30.11.89, under the authority of a responsible competent in radio protection.

Recommendations and Limitations on Use

Recommendations are given for each type of equipment in the joined table I. Wearer has to check if he is using an equipment adapted to the risks entailed. A particular attention has to be brought on the choice of the lead equivalent thickness of the equipment and on the choice of front and back protection.

Table I Personal Protective Equipment Against X-Rays

Trade Name	Model Code	Sizes available (1)	Lead equivalent thickness in mmPb/ 100kV (2)		Recommendations and limitations for use
			Front side	Back side	
Coat Apron	CA09050/25	S, M, L	0,25	0,25	For frontal protection only. To be used by operators in X-Ray examinations room during radiological examinations with or without interventional procedures, where the radiation only comes in the front Intended to protect the main part of the body of the operator. Has to be used with additional protective devices to protect the full body: <u>Thyroid Shields, protective eye glasses or helmets.</u>
	CA09050/35		0,35	0,25	
	CA09050/50		0,50	0,25	
					For protection of the front and back parts of the body.

Double Side Apron	DA090107/50	S, M, L	2x0,25 0,25 = 0,50 (3)	To be used by operators in X-Ray examinations room during radiological examinations with or without interventional procedures. Intended to protect the main part of the body of the operator. Has to be used with additional protective devices to protect the full body: Thyroid Shields, protective eye glasses or helmets.
Skirt and Vest	SV105107/50	S, M, L	2x0,25 0,25 = 0,50 (3)	For protection of the front and back parts of the body. To be used by operators in X-Ray examinations room during radiological examinations with or without interventional procedures. Intended to protect the main part of the body of the operator. Has to be used with additional protective devices to protect the full body: Thyroid Shields, protective eye glasses or helmets.
Kids Apron	KA05045/50	S, M, L	0,50 0,50	For frontal protection only To be used by children patients during Intended to protect the main part of the body and more particularly reproductive organs. Has to be used with additional protective devices to protect the full body: Thyroid Shields, protective eye glasses or helmets
Thyroid Shield	TS00405/35 TS00405/50	S, M, L	0,35 - 0,50 -	To be used in X-Ray examination room during radiological examinations to cover the throid. Should be used along with the apron. Check that an overlapping is realised between the junction of these equipment and that no part is uncovered.
Gonad Protection	GP02025/50	XS, S, M, L	0,50 -	To be used by the patients during radiological examinations, to cover the gonads

(1) The corresponding human body dimensions for each size are given in table 2

(2) For radiation quality of 100 kV with a copper filtration of 0,2 mm

(3) Protection equivalent to 0,50 mmPb by overlapping of two layers with a lead equivalent thickness of 0,25 mmPb

The indications of the present instructions for use can, on no account, substitute to the prescripts set up by the responsible competent in radio protection.

The garments are manufactured according to the standard IEC 1331-1 and IEC 61331-3 which include testing up to a voltage of 100 kV with a copper filtration of 0,2 mm. So, the garment confirms to a minimum lead equivalent thickness as stated on the sewn-in label. For this reason, we guarantee you a suitable protection for X-ray tube voltage at 100 kV with a copper filtration of 0,2 mm. If you wish to use this equipment at another voltage, please contact us.

Ergonomics

-

These equipment have to be adapted to size wearer and correctly adjusted to be effective. The following tables give you the size system:

Size designation

Aprons and Thyroid Shield

Skirt

Size	Height	Chest girth (cm)	Size	Height (cm)	Waist girth (cm)
S	145-175	70-99	S	145-175	56-80
M	145-195	100-119	M	145-195	80-100
L	155-195	120 and above	L	155-195	100 and above

Kids Apron

Size	Height	Age (Years)
S	< 100	3-5
M	100-125	6-8
L	125-145	9-12

Gonad Protection

Size	Height (cm)	Waist girth (cm)
XS	< 145	< 56
S	145-165	56-80
M	145-195	80-100
L	155-195	100 and above

Storage and Life Expectancy

The life expectancy of this equipment is ranging from 5 to 10 years depending very strong on their use and store conditions. For this reason, we recommend:

- Avoid exposure to direct heat and high relative humidity
- Hang Apparel on a hanger after use. Do not fold, crease or wrap it to avoid permanent creasing
- Do not hang on hooks or nail as this will distort the apparel and lead vinyl

For transporting , we recommend you to fold it carefully and place it in its original packaging or an equivalent one.

Cleaning

The special coating of the Medical Index radiation protective clothing prevents that dirt penetrates into the material.

To avoid a damage of the coating

- Clean regularly for dust with sponge or cloth wet in a solution of mild soap and water
- Clean wet stains with a lukewarm detergent and a soft cloth.
- Clean dry stains with a lukewarm detergent, which works in for about 60 minutes,. Then clean with a soft cloth.
- For extremely persistent stains we recommend to use a sodium thiosulfate 10% aqueous solution. Conform to the instructions for use of the product when using it.
- **Please do not use caustic cleaning agents such as alcoholic solvents, gasoline or dilution and do not soak in water or keep under running tap.**

Disinfecting

Do not use any disinfecting with alcohol and do not autoclave.

Inspection

Please inspect your garment thoroughly upon receipt and before each use. We advise you to have a particular attention to :

- Visual inspection: we advise you to:

check the lead equivalent and size labels sewn in the garment to make sure you are using the correct garment.

Check equipment for any visible defects in workmanship and notify us immediately if your garment is not satisfactory. Light spots, small or large, may appear which indicate localised thicker particles. This effect increases x-ray absorption and should be of no concern. A small amount of dark spots/pin holding can appear which is inherent to the manufacturing process and as long there are no dark spots exceeding 5 mm in diameter health physicist have determined they are of no concern. This should not be interpreted as defective manufacturing. **There should be concern if you find dark spots or holes larger than 5 mm or an area which shows many small spots clumped together as well as if dark lines appear as if they usually indicate possible cracks thinning in the material.**

Please contact Medical Index directly in case of inadequacy.

- Radiological Inspection: we advise you to verify regularly the conservation of the radioprotection properties (homogeneity or the attenuation).

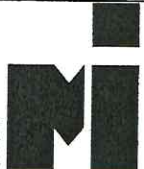
Copy of Label

A label is sewn on each equipment and located:

- 10 cm underneath the left of the sleeve-hole for aprons
- 10 cm underneath the waist for the model Skirt
- at the bottom side for the Gonad Protection and the Thyroid Shield

You will find the following information on it:

- (1) Manufacturer - Responsible for placing product on the market
- (2) Model
- (3) Size: length x width in cm, S, M, L for small, medium or large
- (4) Reference of the Model
- (5) Serial Number (two digits for the months/two digits for the year)
- (6) Lead equivalent thickness for the front side of the garment under 100 kV with copper filtration of 0,2 mm
- (7) Lead equivalent thickness for the back side of the garment under 100 kV with copper filtration of 0,2 mm
- (8) Number of the specific standards
- (9) CE marking and code of organisation in charge of monitoring:
TÜV Product Service GmbH
Ridlerstraße 31
80339 München
- (10) Pictogram meaning that the customer has to look at the instruction for use and more particularly at the cleaning instructions.
- (11) Pictogram for the size



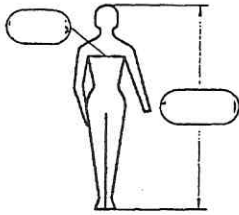
medical index GM BH
 ...made for friends
 Germany

Model:.....
Size:.....
Reference No.:
Serial No.:.....
Front Side:.....
Back Side:.....

According to IEC 1331-1 and IEC 61331-3

 0123





Copy of labels

Label is located 10 cm underneath of the left the sleeve-hole, 10 cm underneath of the waist (Skirt) or at the bottom side of the Gonad Protection.

"MATRIX" for X-Ray Protection Garments

Finally the solution for strong load with disinfection agents

The MATRIX tissue was successful tested with the following disinfection agents:

**Betadine
(Betaisodona)
Octenisept
Octeniderm
Kodan Tinktur forte
Betaseptic Mundipharma
Sterillium classic pure
Desderman pure
u.v.m.**

**100 % halogen free
cleanable up to 95°C
Öko-tex**

starting on October 2015

Bericht

Bestimmung des Bleigleichwertes nach IEC 1331-1

PS Auftrag vom 06.02.2004 Herr Wittmann

Sehr geehrter Herr Wittmann,

Die Überprüfung der zugesandten Prüfmuster ergab folgende Bleigleichwerte:

Prüfmuster	Soll PB - Wert	Ermittelter PB - Gleichwert in mm PB			
		60 KV	81 KV	100 KV	125 KV
Schürze CA 100 SS / 50 (vorne)	0,50	0,58	0,51	0,475	0,48
Schürze CA 100 SS/ 35 (vorne)	0,35	0,41	0,35	0,345	0,345
dito (hinten)	0,25	0,345	0,29	0,28	0,25
Schürze CA 100 SS/ 25	0,25	0,305	0,255	0,24	0,245

Bau und Betrieb

Niederlassung München
Abteilung
Medizin- u. Röntgentechnik

Westendstraße 199
80686 München
Telefon (0 89) 57 91-18 24
Telefax (0 89) 57 91-22 71
www.tuev-sued.de
E-mail Franz Josef .Dauster
@tuev-sued.de

München, 01.03.2004
BB-MT3-MUC/Da Auftrag
06_02_2004S.doc

Das Dokument besteht aus:
1 Seiten

TÜV Süddeutschland
Bau und Betrieb GmbH
Aufsichtsratsvorsitzender:
Dr. Axel Stepken
Geschäftsführer:
Roland Ayx
Dr. Udo Heisel
Sitz: München
Amtsgericht München
HRB 96 869

Mit freundlichen Grüßen

F. J. Dauster
Franz Josef Dauster



1 PRIEDAS

Protokolas

Švino ekvivalentinės reikšmės nustatymas pagal IEC 1331-1

2004 02 06 užsakymas, užsakovas Wittmann

Gerbiamasis Wittmann,

atsiųstų pavyzdžių patikra davė tokius rezultatus:

Tikrinamas pavyzdys	Užduotoji PB reikšmė	Nustatytoji PB ekvivalentinė reikšmė, mm			
		60 KV	81 KV	100 KV	125 KV
Prijuostė CA 100 SS / 50 (priekyje)	0,50	0,58	0,51	0,475	0,48
Prijuostė CA 100 SS / 35 (priekyje)	0,35	0,41	0,35	0,345	0,345
Tas pat (ant nugaros)	0,25	0,345	0,29	0,28	0,25
Prijuostė CA 100 SS/ 25	0,25	0,305	0,255	0,24	0,245

Su draugiškais linkėjimais,

/parašas/

Franz Josef Dauster

TUV PIETŲ VOKIETIJA

Statyba ir darbas

Miuncheno filialas

Medicinos ir rentgeno technikos skyrius

Westendstrasse 199

80686 Miunchenas

Tel. (089) 5791-1824

Faks. (089) 5791-2271

www.tuev-sued.de

E. p.:

Franz.Josef.Dauster@tuev-sued.de

Miunchenas, 2004 03 01

BB-MT3-MUC/Da Auftrag

06_02_2004S.doc

Dokumentą sudaro:

1 lapas

„TUV Suddeutschland Bau und Betrieb GmbH“

Stebėtojų tarybos pirmininkas

dr. Axel Stepken

Bendrovės vadovai:

Roland Ayx

Dr. Udo Heisel

Buveinė: Miunchene

Apylinkės teismas Miunchene,

reg. Nr. HRB 96 869

Spaudas: „TUV PRODUCT SERVICE GMBH“

Ridlerstrasse 65, D-80339 Miunchenas /parašas/.

Ženklas: TUV.