MHK MEDİKAL TEKSTİL SAN. VE TİC. LTD. ŞTİ.

DISPOSABLE STERILE SURGICAL DRAPES, GOWNS AND PROCEDURE PACKS (TRAYS) BIOCOMPABILITY ASSESMENT REPORT

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1. Revision History

Revision	Date	Revision / Reason for Change
00	15.08.2013	First Issue
01	30.03.2022	

1. Objectives and References

1.1. Purpose of The Study

This study was prepared for the purpose of reporting the biological evaluation study carried out on the basis of ISO MHK MEDİKAL TEKSTİL SAN. VE TİC. LTD. ŞTİ.10993 Serial standards in order to evaluate the safety and performance of DISPOSABLE STERILE SURGICAL DRAPES, GOWNS AND PROCEDURE PACKS (TRAYS) produced by our company in line with valid biological data. The scope of the report includes product information, biological evaluation scope and methodology, evaluation of test reports and evaluation of the data obtained and biological evaluation results obtained in line with the analysis of the data.

1.2. References

Most of the contents of this study are prepared according to the following standards:

1) EN ISO 14971:2012 Medical Devices – Application Of Risk Management To Medical Devices
2) EN ISO 10993-1:2018 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
3) EN ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
4) EN ISO 10993-10:2021 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization
5) EN ISO 10993-9:2021 Biological evaluation of medical devices- Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2019)
6) EN ISO 10993-12:2021 Biological evaluation of medical devices- Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
7) ISO 10993-18:2020 Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
8) ISO 10993-11:2017, Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

2. Product Description

2.1.Product Information

Detailed product description is defined in TD-02.01 Device description and specification document.

2.2. Product Models

TD-02.01 Device description and specification document as part of the report.

3. Test Sample Selection Justification

Ürettiğimiz ürünleri üretim aşamaları ve kullanılan hammaddeler dikkate alınarak iki gruba ayırdık. Her ürün grubunda tüm üretim aşamalarını ve hammaddeleri kullanarak üretimini gerçekleştirdiğimiz ürünlerden Procedure Pack(Trays) olarak paketlenmiş ve steril olmuş ürün içerisinden Tek Kullanımlık Steril Reinforced Surgical Gown ve OPU Drape seçilmiştir.

3. Component Description

Detailed product description is defined in TD-02.01 Device description and specification document.

4. MHK MEDİKAL TEKSTİL SAN. VE TİC. LTD. ŞTİ. Üretim Süreçlerinin Biyouyumluluğa Etkisi

In this evaluation study, MHK MEDİKAL TEXTILE SAN. AND TİC. LTD.. STI. products that have passed through all processes have been used to show the effect of all processes on production.

5. Biological Classification Evaluation

5.1.1. Biological Classification

5.1.2. ISO 10993-1 Biological Classification

Belirli güvenlik değerlendirme programları International Organization for Standardization (ISO) ISO 10993 standartlarını uygulamaktadır. Ürünlerimizin biyouyumluluğunu değerlendirmek için tüm prosesleri temsil edecek şekilde hazırlanan ürünlerimiz üzerinde, ISO 10993-1:2018'de Table A.1' e göre Category : Surface Medical Device Contact: Intact Skin Contact Duration : **A – limited**(≤24 h) 24 saatten az veya eşit olal tıbbi cihaz olarak değerlendirilmiştir.

Table A.1 — Endpoints to be addressed in a biological risk assessment

Medical device categorization by			Endpoints of biological evaluation														
Nature of body contact		Contact duration															
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – Long term (>30 d)	Physical and/or chemical information	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Material mediated pyrogenicity[a]	Acute systemic toxicity[b]	Subacute toxicity[b]	Subchronic toxicity[b]	Chronic toxicity[b]	Implantation effects[b,c]	Hemocompatibility	Genotoxicity[d]	Carcinogenicity[d]	Reproductive/ developmental toxicity[d,e]	Degradation[f]
Surface medical device	Intact skin	A	X[g]	E[h]	E	E											
		B	X	E	E	E											
		C	X	E	E	E											
	Mucosal membrane	A	X	E	E	E											
		B	X	E	E	E		E	E			E					
		C	X	E	E	E		E	E	E	E	E		E			
	Breached or compromised surface	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E					
		C	X	E	E	E	E	E	E	E	E	E		E	E		
Externally communicating medical device	Blood path, indirect	A	X	E	E	E	E	E					E				
		B	X	E	E	E	E	E	E				E				
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		
	Tissue/ bone/ dentin[i]	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Circulating blood	A	X	E	E	E	E	E					E	E[j]			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		
Implant medical device	Tissue/bone[i]	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Blood	A	X	E	E	E	E	E				E	E	E			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		

[a] Refer to ISO 10993-11:2017, Annex F.

[b] Information obtained from comprehensive implantation assessments that include acute systemic toxicity, subacute toxicity, subchronic toxicity and/or chronic toxicity may be appropriate if sufficient animals and timepoints are included and assessed. It is not always necessary to perform separate studies for acute, subacute, subchronic, and chronic toxicity.

[c] Relevant implantation sites should be considered. For instance medical devices in contact with intact mucosal membranes should ideally be studied/ considered in contact with intact mucosal membranes.

[d] If the medical device can contain substances known to be carcinogenic, mutagenic and/or toxic to reproduction, this should be considered in the risk assessment.

[e] Reproductive and developmental toxicity should be addressed for novel materials, materials with a known reproductive or developmental toxicity, medical devices with relevant target populations (e.g. pregnant women), and/or medical devices where there is the potential for local presence of device materials in the reproductive organs.

[f] Degradation information should be provided for any medical devices, medical device components or materials remaining within the patient, that have the potential for degradation.

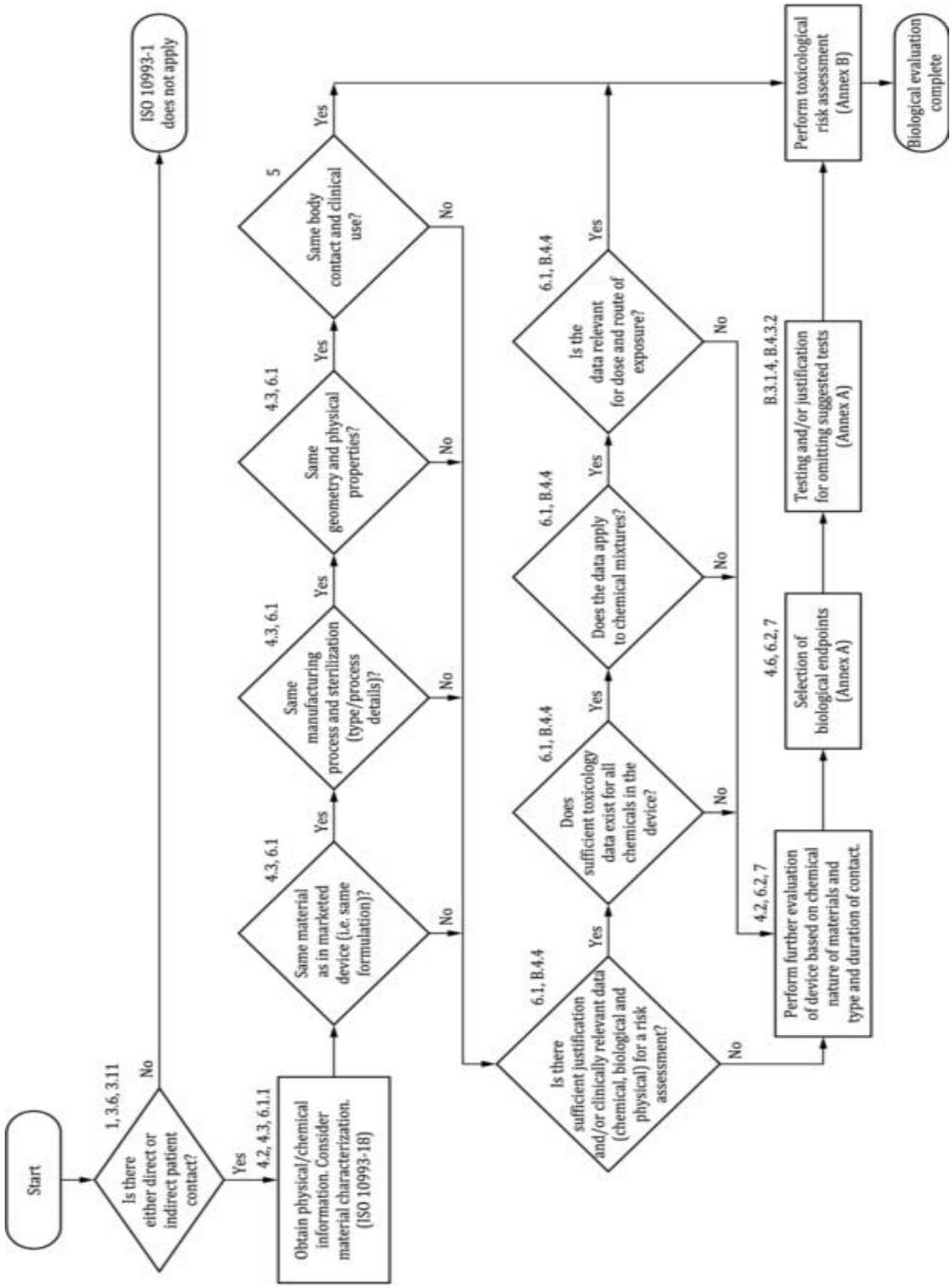
[g] X means prerequisite information needed for a risk assessment.

[h] E means endpoints to be evaluated in the risk assessment (either through the use of existing data, additional endpoint-specific testing, or a rationale for why assessment of the endpoint does not require an additional data set). If a medical device is manufactured from novel materials, not previously used in medical device applications, and no toxicology data exists in the literature, additional endpoints beyond those marked "E" in this table should be considered. For particular medical devices, there is a possibility that it will be appropriate to include additional or fewer endpoints than indicated.

[i] Tissue includes tissue fluids and subcutaneous spaces. For gas pathway devices or components with only indirect tissue contact, see device specific standards for biocompatibility information relevant to these medical devices.

[j] For all medical devices used in extracorporeal circuits.

5.2. Ürünlerinin Biyolojik Değerlendirmesi için Sistematik Bir Yaklaşıma Yardımcı Olmak için Akış Şeması



The table result was evaluated according to ISO 10993-1:2018 standard.

6. Review Criterias

Biocompatibility studies are reviewed if the following conditions are carried out and tests are repeated if necessary.

1. Raw material and raw material supplier change
2. Significant changes in production processes
3. Change of production location

7. Final Evaluation

Disposable Surgical Drapes are disposable surgical materials that are laid on and under the patient during the operation, used in different models and features according to the type of operation, and used to prevent the contamination of the surgical wound by skin-derived microorganisms.
All drapes used during the surgery should have the least pilling value and should be draped and non-potty structure. However, a light and breathable structure is a necessary criterion for the patient not to sweat. Depending on the type of operation performed, liquid resistance is required in some operations and liquid absorbency is required in some operations. However, the amount of liquid released in some operations may exceed the protection limits of standard materials. In such operations, polypropylene film layer is used in order to provide absolute impermeability against liquids and therefore bacteria. Thus, it is ensured that the patient and the operator are protected from liquids and therefore from infections caused by liquids. The film layer used must be very tear resistant and light; With this feature, it can be applied easily and provides comfort during the operation.
The most important features sought in surgical gowns are resistance to the passage of liquid and microorganisms, air permeability and comfort and convenience to the operator during use. lthough it is thought that reusable aprons have these desired features, the advantages of disposable aprons over multi-use are quite high.
The most used fabric structure in disposable covers and aprons is non-woven fabrics known as polypropylene structure. The drapes have holes for surgical openings or incision openings. The most commonly used fabric structure in disposable aprons is SMS or SSMMS, known as 3- or 5-layer polypropylene structure. SMS material is more popular because of its price. For SMS aprons, the weight of 45-70 gr/m2 should not be exceeded. However, even spunbond surgical gowns are encountered, although they are not at all suitable for working conditions. However, spunbond material is not suitable for surgical gowns, as it does not have sufficient protective properties and ease of use but is suitable for clothing such as patient gowns that are not used in surgical environments.
In the examinations, the most suitable material for use as a disposable surgical gown is the spunlace nonwoven fabric type produced by Dupont under the name Sontara. Sontara, which is a mixture of 55% cellulose - 45% polyester and has an average weight of 68 gr/m2, has become the most preferred material by conscious users due to its cellulose content and superior production technology. Because the aprons made from this cellulose-containing raw material provide the best fit for the operator's skin during the operation.
The ribs used on the sleeves of the gowns used in the operating room should be made of cotton materials so that they will fully grasp the wrists of the surgical team but will not tighten during long operations. It is seen that the ribs used in the aprons produced by some companies are made of 100% polyester, which is an important factor that disturbs the

operator, especially in long-term operations. The piping used on the neck should be soft and non-irritating to the skin. The breathing feature of this piping and fabric absorbs sweat during long operations and relaxes the operator.
The three main requirements for surgical gowns are liquid tightness, absorbency and air permeability. Even in the best works, these are difficult to coexist. However, from a hygiene point of view, liquid proofing should be considered as the most important feature of the garment. When the nonwoven fabrics of which liquid-proof disposable surgical gowns are made are tested according to the wet bacterial permeability test, the test organisms should not penetrate the material under the defined pressure and mechanical load.

Biological evaluation report ISO 10993-1:2018 standard Table A.1 is classified according to the categories specified in the article. Tests to be performed according to the body area and contact time of the product have been determined.

As a result of this measure taken by the manufacturer.

MHK MEDİKAL TEKSTİL SAN. VE TİC. LTD. ŞTİ. Within the scope of DISPOSABLE STERILE SURGICAL DRAPES, GOWNS AND PROCEDURE PACKS (TRAYS) ISO 10993-1:2018 standard, the product has been proven to be biologically safe compared to the usage times and peer product evaluations and product test results.

During the evaluation.

- expected service life.
- the effects of any intended processing or reprocessing.
- Patient exposure in the worst case. It's been considered.

The biological assessment report should be updated annually with risk management report and risk benefit analysis studies. Risk benefit analysis should be supported by PMS reports. PMS studies to be carried out within the scope of MEDDEV 2.12.1 and MEDEV 2.12.2 are reassessed every year in terms of biological evaluation and the report will be updated with the study.

Biocompability Tests Reinforced Surgical Gowns	Standards Applied	Evaluation
Cytotoxicity Report Number: IVT-20-048 Report Date: 18.03.2020	EN ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity	Uygundur.
Skin Sensitization Report Number: 2020.04.84	EN ISO 10993-10:2021 Biological evaluation of medical devices- Part	Uygundur.

Report Date: 04.04.2020	10: Tests for irritation and skin sensitization	
Irritation Report Number: 2020.03.62 Report Date: 09.03.2020	EN ISO 10993-10:2021 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Uygundur.

Biocompability Tests Surgical OPU Drape	Standards Applied	Evaluation
Cytotoxicity Report Number: IVT-20-049 Report Date: 18.03.2020	EN ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity	Uygundur.
Sensitization Report Number: 2020.04.083 Report Date::04.04.2020	EN ISO 10993-10:2021 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Uygundur.
Irritation Report Number: 2020.03.63 Report Date: 09.03.2020	EN ISO 10993-10:2021 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Uygundur.

7. ANNEXES

1. Cytotoxicity Test Report (2 pcs)

2. Sensitization Test Report (2 pcs)

3. Irritation Test Report (2 pcs)