LATEX Free Declaration

LATEX Free Declaration

We,

DEXXON ENERJİ SAN. VE TİC. A.Ş

YENİBOSNA MERKEZ MAH., 29 EKİM CAD., İSTANBUL VİZYON PARK OFİS BLOKLARI, PLAZA: 1 FLOOR : 8 BAHÇELİEVLER / İSTANBUL / TURKEY

declare under our sole responsibility that the PPE product listed below

Product Description	NON REUSABLE FFP2 NR FACE MASK
Article No	DXNMD NRFM04
Type	FFP2 NR
Manufacturer	DEXXON ENERJİ SAN. VE TİC. A.Ş
Brand Name	DEXXON MEDICAL
Applicable Harmonised Standards	EN 149: 2001 + A1: 2009

Dexxon Medical Face Masks Position on Natural Rubber Latex

We declare that the product described above meets the requirements of the relevant provisions of the regulation as a result of the EU Type examination according to Annex 5 of the PPE Personal Protective Equipment Regulation (2016/425 / EU)
This Declaration of Conformity covers the PPE device as specified in the product list belonging to this declaration.

Dexxon Medical does not use Natural Rubber latex in our materials, packaging, processing aids, or the handling of product.
Dexxon Medical does not allow latex into our facilities and we declare we are a Latex Free business.

As a manufacturer, we now declare that our above medical and protective face masks are free of latex, free of silicones and free of PVC.
The material and parts named above, including any of their possible decomposition products, are not known to cause adverse effects to user hygiene or health, nor are likely to cause irritation, during normal use.
The materials used in the product are produced in accordance with the human body and do not have any allergic properties.
Because of the product is used in the health sector, skin sensitivity, irritation and conformity assessment processes are supported by biocompatibility tests.

Sincerely,

Murat Koç
President
09.02.2022

DEXXON MEDICAL

MATERIAL DECLARATION AND BIOCOMPATIBILITY TESTS

The material and parts named above, including any of their possible decomposition products, are not known to cause adverse effects to user hygiene or health, nor are likely to cause irritation, during normal use.

Compatibility with the skin

The materials used in the product are produced in accordance with the human body and do not have any allergic properties.
Because of the product is used in the health sector, skin sensitivity, irritation and conformity assessment processes are supported by biocompatibility tests.

The skin compatibility (biocompatibility) performance tests of the product are presented in ANNEX:

I CONFIRM THAT THE DECLERATION IS TRUE AND VALID ☒

We declare that the products/materials recommended for maintenance, cleaning and disinfecting do not have any adverse effect on the PPE or the user when applied in accordance with the relevant instructions.

8.2 Declaration – Supply of User Information (*Annex III k)*

We declare that the user information accompanies each smallest commercially available unit.

I CONFIRM THAT THE DECLERATION IS TRUE AND VALID ☒

Approved by

Murat Koç
General Manager

DEXXON MEDICAL

BIOCOMPABILITY TESTS

- CYTOTOXICITY TESTS
- DERMAL IRRITATION TEST ANALYSIS
- SENSITIZATION TESR RESULT REPORT

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OXIGEN ANALİZ ÖZEL KONTROL LABORATUVARI
Çakmaklı Mah. Hadımköy Bağlantı Yolu Ufuk Plaza
No:57 K:1 D:8 34500 Büyükçekmece/İSTANBUL
INSPECTION AND ANALYSIS REPORT

TÜRKAK
Test
TS EN ISO/IEC 17025
AB-0953-T

AB-0953-T
2021-C-00627
03-2021

Report Number	: 2021-C-00627	Date of Report	: 12/03/2021
Purpose of Analysis	: Cytotoxicity Test		
Costumer name/addres	: DEXXON ENERJİ SAN VE TİC.A.Ş /Istanbul Vizyon Park Ofis Blokları Yeni Bosna Merkez Mah 29 Ekim Cad No:3 Plaza : 1 Kat : 8 No: 84 / İstanbul		
Name and identity of test item	: Non-Reusable Protective FFP2 NR Colored Filtering Half Mask		
Code of sample	: DXNMD-NRFM04 FFP2 NR COLORED MASK		
Package of Sample/Quantity	: 3 Piece		
Date of receipt of test item	: 04/03/2021		
Date of Test/End of test	: 05/03/2021 - 12/03/2021		
Number of pages	: 6		

Analysis	Unit	Result	Limit Of Measurement	Recovery	Uncertainity of Meas.	Analysis Metod	Com.
1-*InvitroCytotoxicity Test		it is not Cytotoxicity				TS EN ISO 10993-5((Biologicalevaluation in medicaldevicesPart 5: Test for in vitrocytotoxicity TS EN ISO 10993-12 (Biologicalevaluation in medicaldevicesPart 12: Test samplepreparationand Reference Materials..	U

Explanation:

1. Experiment environment

CELL LINE:L929 (Mouse Fibroblast cell)

CultureMedium : DMEM+ L-Glutamin
Fetal Bovine Serum

Penisilin- Streptomisin

Blank : Sterile cell culture medium

NEGATIVE CONTROL: Polietilen Kryo Tüp + Cell

POSITIVE CONTROL: Natural RubberLatex+ Cell

2.METHOD OF APPLICATION

Extraction was performed according to TS EN ISO 10993-12 standard. The samples were placed in a waterbath at a rate of 50 rpm at 37ºC for 24 hours in a 10% serum-containing cellculture medium of the size specified in the standard. The extraction was then terminated and the extract obtained was used within 24 hours.

3.ANALYSIS METHOD

Qualitative Evaluation:

Cells were expected to become confluent by sowing 6 well plates.
Subsequently, the 37°C 5% CO_2 sample was exposed to negative, positive control and sample extracts for 24 hours. After incubation, cells were microscopically examined ande valuated according to TS EN ISO 10993-5 standard.

Quantitative Evaluation:

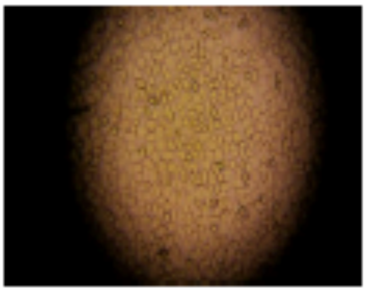
In the study, it was applied according to the "TS EN ISO 10993-5 / XTT Cytotoxicity Experiment" standard. The 96-well plate was counted as 100 / well and the cultured cells were incubated for 24 hours to provide 80% confluency. Subsequently, the cells were exposed to 1/1 - dilutions of the sample extract for 4 hours.
At the end of the process, 1 mg / mL XTT was added to the wells and the plates were incubated for 3 hours at 37 ° C in 5% CO_2. The assay was terminated by the addition of isopropyl alcohol to the wells and the% viability values were calculated by measuring the color change in the plates (570-650 nm) spectrophotometer.

4. TEST RESULTS

Qualitative Evaluation:

The qualitative evaluation was made according to Table 1 in TS EN ISO 10993-5 standard.

a.Negatif Kontrol



b. Pozitif Kontrol

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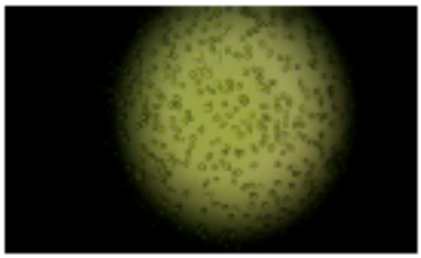
INSPECTION AND ANALYSIS REPORT

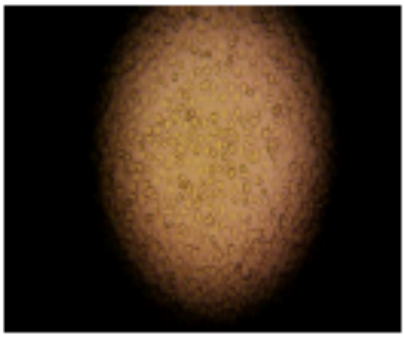
TÜRKAK AB-0823-T

AR-0853-T
2021-C-00627
03-2021

Report Number : 2021-C-00627 Date of Report : 12/09/2021



c. Nutrient



Must No.	Test Material	Reaction	Situations of Cultures
1	Negative Control	0	Discretecytoplasmicgranules, celldisruptionno, nodecrease in cellproliferation
2	Positive Control	4	Nearlyallcelllayers have been destroyed
3	Sample	0	Discreteintracytoplasmicgranules, no cell destruction, no decrease in cell proliferation

Quantitative Evaluation:

(TS EN ISO 10993-5 / XTT Cytotoxicity Test)

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INSPECTION AND ANALYSIS REPORT

TÜRKAK AB-0903-T

AR-0953-T
2021-C-00627
03-2021

Report Number : 2021-C-00627 Date of Report : 12/08/2021

DILUTION RATIOS						
TEST NUMBER	100%	75%	50%	25%		
1. AGAIN	0,976	1,114	1,224	1,336		
2. AGAIN	0,835	1,138	1,203	1,339		
3. AGAIN	0,987	1,125	1,229	1,351		
AVERAGE	0,932	1,125	1,218	1,342		
POSITIVE CONTROL	100%	75%	50%	25%		
1. AGAIN	0,104	0,206	0,321	0,426		
2. AGAIN	0,106	0,208	0,314	0,441		
3. AGAIN	0,108	0,201	0,325	0,405		
AVERAGE	0,106	0,205	0,320	0,424		
Negative Control(%100)	1.Again	2.Again	3.Again			
%100 Ekstrakt	1,109	1,111	1,112			
AVERAGE	1,11					
Blank	A2	A3	A4	A5	A6	A7
	0,888	0,990	0,999	0,996	1,010	1,002
	H2	H3	H4	H5	H6	H7
	0,991	0,992	0,994	0,999	1,080	1,099
AVERAGE	1,003					

Viab.%=100 X OD450e/OD450b

OD450e : % 100 optical density of the sample extract

OD450b : Average value of optical density of blank

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INSPECTION AND ANALYSIS REPORT

TÜRKAK AB-0953-T

AB-0953-T
2021-C-00627
03.2021

Report Number : 2021-C-00627 Date of Report : 12/08/2021

Test SampleViab.% : % 93

PozitiveControlViab.% :% 11

Negative ControlViab.% : %111

REVIEWS :

1.The test was carried out in accordance with the standard "TS EN ISO 10993-5 Biological evaluation of medical devices-Part 5: extrac or poreal cytotoxicity tests".

2.The effect of the extracts on the cells for qualitative evaluation was examined microscopically and evaluated by the qualitative morphological grading of the cytotoxicity of the extracts given in the standard "Table 1. Accordingly, the negative control showed no toxic effect on the cells (0), and the positive control showed toxicity as high as expected (4). Since the cytotoxic effect of the sample extracts was not toxic when examined, it wasevaluated as (0).According to the standard used, as indicated in table 1, the presence of a larger rating value of (2) is considered a cytotoxic effect.

3.The "TS EN ISO 10993-5 / XTT Cytotoxicity Experiment" wasused as the quantitative evaluation method and the obtained results (Table 2) were evaluated statistically. Results from the negative and positive controls used and test validity criteria are met.

In this experiment, the effects of 1/1 dilutions of sample extract on cells were examined; The complete dilution of extract from the sample (1/1) andviability was 93 %.

According to the standard used, this value is lessthan 70%, indicatingthatthere is nocytotoxic effect on thesampleextracts since there is a cytotoxicityindicator.

Chart1.Qualitative morphological grading of cytotoxicity of extracts

Degree	Reaction	Situations of Cultures
0	No	Discreteintraoplasma granules, no cell destruction, no decrease in cell proliferation
1	Very little	There are more than 20% of cells that are not round, poorly adherent, and contain few or no intracellular granules, or morphologicallyaltered, rarely destroyed cells, only slight growth inhibition can be observed
2	Light	Round cell number is less than 50%, nointraplasiongranules, observable cell inhibition is not more than 50%
3	Middle	The number of cells rounded or destroyed is not more than 70%, the cell layers are not completely degraded, the observable cell inhibition is more than 50%
4	Severe	Nearly all cell layers have been destroyed

(*) Analysis method is in scope of accreditation.
Evaluation:
Theabovementionedvalueswere determined as theresultof theinspectionandanalysis.
1.No part of thisanalyticalreport can be usedaloneorseparately. Unsignedandunsealedreportsaredefined.
2.Analysis resultsarevalidfortheabovesample
3.When necessary, "MeasurementUncertainty" and "Recover" informationaregiventogetherwiththeanalysisresults
4.Judicial andadministrativeproceduresto be usedforadvertisingpurposes. It can not be partiallyreproducedandpublishedwithoutpermission
5. Measurement uncertainty is applied in favor of the customer in Quantitative Analysis.
6. Decision Rule is not applied in microbiological analyses.

Abbreviations: N.A: Not Detected A:Appropiate IA: Inappropriate AF: AssessmentFailedEVL :Evaluation

Cell Microbiology Unit Responsible
Havva Lamia Demir

Responsible of theDepartment of SampleAdmission
Kadriye ŞEREF

Approved by
13/09/2021
Mehmet Nur ERAT
Laboratory Manager

DEXXON® MEDICAL

BIOCOMPABILITY TESTS: DERMAL IRRITATION

Technical Universal Verification	**TECHNICAL UNIVERSAL VERIFICATION BELGELENDİRME VE EĞİTİM HİZ. LTD. ŞTİ.** Macun Mahallesi ATB İş Merkezi A Blok No: 3 Yenimahalle / ANKARA Tel: +90 312 231 82 02 & E-Mail. info@techcert.com.tr & www.techcert.com.tr		NAC NAC-003-TL
Test Adı/Testing Name: **DERMAL İRRİTASYON &** **DERMAL IRRITATION**	Rapor Numarası/Report No	KBYU0005/2021-03/BYU/1451	

** This report ISO 17025: has been prepared within the scope o general conditions for the competence of testing and calibration laboratories

BİYOUYUMLULUK TEST LABORATUVARI
BIOCOMPATIBILITY TESTING LABORATORY

FİRMA ADI/COMPANY NAME:	**DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.**
ADRES/ADDRESS:	**İSTANBUL VİZYON PARK OFİS BLOKLARI YENİBOSNA MERKEZ MAH. 29 EKİM CAD. NO:3 PLAZA 1 K:8 NO:84 BAHÇELİEVLER – İSTANBUL - TURKEY**
TESTİN ADI/TESTING NAME:	**DERMAL IRRITATION**
TEST STANDARDI/TEST STANDARD:	**TS EN ISO 10993-10: 2014-02**
TİCARİ MARKA (VARSA)/COMMERCIAL BRAND (IF YOU HAVE):	-
ÜRÜN ADI/PRODUCT NAME:	**FFP2 NR DISPOSABLE VALVE FACE MASK**
NUMUNE KAYIT NO/SAMPLE REGİSTRATİON NO:	**KBYU0015/2021**
NUMUNE LOT NUMARASI/LOT NUMBER OF SPECIMENS:	**DEXXON MEDICAL DXNMD-NRFMO4 FFP2 NR**
NUMUNE SAYISI/NUMBER OF SPECIMEN:	**6**
TEST BAŞLAMA TARİHİ/TEST START DATE:	**02.03.2021**
TEST BİTİŞ TARİHİ/TEST END DATE:	**05.03.2021**
RAPOR TARİHİ/REPORT DATE:	**22.03.2021**
KULLANILAN CİHAZLAR/USED DEVICES:	-
EA TANIMLAMASI/EA DESCRIPTION:	**Asia Pasific Accreditation Association (APAC) ISO/IEC 17025: 2017 CABs National Accreditation Center (NAC) by accredited the general requirements for the adequacy of the test and calibration laboratoires standard for the recognition of test report. It proves the traceability to national measurement standards that are defined in the International System of Units (SI), realizing the units.**

BİYOUYUMLULUK TEST SORUMLUSU **BİYOKİMYAGER** **YEŞİM ÖZKUL**	**VETERİNER HEKİM** **SONER AKTEMUR**	**TECHNICAL UNIVERSAL VERIFICATION**

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Test Adı/Testing Name: **DERMAL İRRİTASYON & DERMAL IRRITATION**	Rapor Numarası/Report No	KBYU0005/2021-03/BYU/1451	

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BİYOUYUMLULUK TEST LABORATUVARI
BIOCOMPATIBILITY TESTING LABORATORY

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BIOCOMPATIBILITY TESTING LABORATORY

DERMAL IRRITATION TEST RESULT REPORT

NAME OF TEST

ISO 10993-10 STANDARD

DERMAL IRRITATION TEST

TEST REQUESTED INSTITUTION AND SPECIMEN NAME

DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.

FFP2 NR TEK KULLANIMLIK VALFSİZ YÜZ MASKESİ

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BİYOUYUMLULUK TEST LABORATUVARI
BIOCOMPATIBILITY TESTING LABORATORY

1. GENERAL INFORMATION ABOUT THE TEST

Test Name and Guide	TS EN ISO 10993-10 Biological evaluation of medical devices chapter 10: Tests standard for irritation and skin sensitivity
Test Requesting Institution	**DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.**
Test Report Number	KBYU0005/2021-03/BYU/1451
Test Start Date	02.03.2021
Test Ending Date	05.03.2021
Test Reporting Date	22.03.2021
Purpose	The test was intended to evaluate the potential of the sample described below to cause dermal irritant effects.

2. INFORMATION ABOUT THE SPECIMEN

Specimen Acceptance Date and Time	28.01.2021
Specimen Recording Number	KBYU0014/2021
Specimen Lot Number	DEXXON MEDICAL DXNMD-NRFMO4 FFP2 NR
Name of Specimen	FFP2 NR DISPOSABLE VALVE FACE MASK
Number of Specimen	5
Specimen Taken Moment Receive	SOLID
Way the Specimen Was Brought	HAND BY RECEİVE
Information About Witness Specimen	Preserve TECHCERT laboratory for 1 year

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BIOCOMPATIBILITY TESTING LABORATORY

3. INFORMATION ABOUT TEST ANIMALS TAKEN IN THE TEST

Species	Rabbit
Kind	New Zealand Rabbit
Source	Kobay DHL A.Ş.
Gender	Male
Weight Range	2-2,5 kg
Age	Young Adult
Familiarization Period	5 days
Number of Animal Used	3 piecies

4. INFORMATION ABOUT USED CHEMICAL AND MEDIUM

Test Animals Maintenance	Chapter 2: Requirements for Animal Welfare are made in accordance with its standards.
Forage	Ad-libitum is done feeding.
Water	Water, be given ad-libitum as suitable drinkers.
Micro Maintenance Conditions	Each test animal was identified and placed in appropriate cages.
Macro Maintenance Conditions	Provides 12 hours of night and 12 hours of daytime environment; %30-70 damp and 17- 23 °C environment is provided. temperature and damp are checked instant daily.
Test Team	Tests are carried out by trained and suitably qualified people.
Test Animal Selection	Healthy, disease-free and under the supervision of a veterinarian it was selected by passing.

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Test Adı/Testing Name: **DERMAL İRRİTASYON & DERMAL IRRITATION**	**Rapor Numarası/Report No**	**KBYU0005/2021-03/BYU/1451**	

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5. INFORMATION ABOUT THE TEST METHOD

TS EN ISO 10993-10 Biological evaluation of medical devices chapter 10: According to the requirements of the test standard for irritation and skin sensitivity, the maintanence conditions of the test animals used in the test were carried out by considering ISO 10993-2 and the preparation of the specimen used in the test and the reference materials ISO-10993-12 standards.
Dermal Irritation Tests; Subsequently the skin application, the animals were observed at different time intervals and the results were evaluated.

6.DERMAL APPLICATION

Specimen; Prepared according to the "Standard surface areas and extract liquid volumes chart" in the standard of TS EN ISO 10993-12 "Specimen Preparation and Reference Materials". As a positive control; Sodium lauryl sulfate (SLS), previously known to have an irritant effect, has been determined. As a negative control; Serum Physiological, previously known to have no irritant effect.

Test and control specimen were applied to the back region of the test animals, whose weights were recorded in Table 1, topically for 4 hours to the skin in the regions and volumes indicated in Figure 1. At the end of this period, bandages were opened, samples were taken and the applied areas were marked. Test materials remaining in the area were washed with warm water. After the procedure the test zones were observed at the 1st,24th,48th and 72nd hours and the specimen were evaluated by considering the criteria in table 2. The evaluation results that should be given according to the score obtained are recorded in Table 3.

Test start date	02.03.2021
Test ending date	05.03.2021

TS EN ISO 10993-10 Biological evaluation of medical devices chapter 10: Biocompatibility test was applied according to the test standard for irritation and skin sensitivity. Animals TS EN 10993-2: 2006 Biological Evaluation of Medical Devices - Part 2: It has been prepared in accordance with the principles of Requirements for Animal Welfare. The test was carried out so as to evaluate the sensitizing potential of the specimen.

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Test Adı/Testing Name: **DERMAL İRRİTASYON & DERMAL IRRITATION**	Rapor Numarası/Report No	**KBYU0005/2021-03/BYU/1451**	

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BİYOUYUMLULUK TEST LABORATUVARI
BIOCOMPATIBILITY TESTING LABORATORY

Solution preparation date	26.02.2021
Solution preparation know how	Chapter 12: According to specimen preparation and reference materials standard; X If specimen solid; "The specimen was prepared by keeping the specimen at 37°C for 72 hours according to the chart of standard surface areas and extract liquid volumes. Subsequently, it was impregnated with a 25x25 mm four-layer gauze and applied to the skin. o If specimen liquid; directly impregnated with 25x25 mm four-layer gauze and applied to the skin. Serum Physiological impregnated with 25x25 mm four-layer gauze was used as a control specimen

CRANIAL TIP

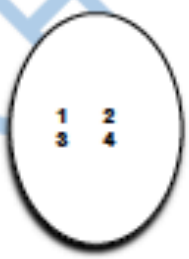

FIGURE 1

CAUDAL TIP

Technical Universal Verification	**TECHNICAL UNIVERSAL VERIFICATION BELGELENDİRME VE EĞİTİM HİZ. LTD. ŞTİ.** Macun Mahallesi ATB İş Merkezi A Blok No: 3 Yenimahalle / ANKARA Tel: +90 312 231 82 02 & E-Mail: info@techcert.com.tr & www.techcert.com.tr		NAC NAC-003-TL
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BİYOUYUMLULUK TEST LABORATUVARI
BIOCOMPATIBILITY TESTING LABORATORY

DERMAL APPLICATION

The specimen were applied as shown in Figure 1 after shaving the test animals (their weights are recorded in Table 1) one day prior to the application to provide sufficient application area (10 cm x 15 cm) in the back area. After covering the samples with 2.5 cm x 2.5 cm sterile gauze, the entire application area was wrapped with a bandage. The samples to be tested for 4 hours were applied to the area. At the end of this period, bandages were opened, samples were taken and the applied areas were marked. Test materials remaining in the area were washed with warm water.

Figure 1 Zone 1: Specimen

Figure 1 Zone 2: Positive Control

Figure 1 Zone 3: Negative Control

Figure 1 Zone 4: Specimen

Dermal Application start date and time	02.03.2021 11:45
Dermal Application ending date and time	02.03.2021 15:45

After the process, the test zones were observed at the 1st, 24th, 48th and 72nd hours and samples were evaluated considering the criteria specified in Table 2. Observations 72 hours after administration were not taken into account. All erythema and edema scores were collected separately for each sample at 24, 48 and 72nd hours in each rabbit. The primary irritation score for a rabbit was calculated by dividing all scores by six. The primary irritation index for the test sample was calculated by dividing the sum of each animal's primary irritation index by three. Primary irritation was also calculated for the controls. This score is subtracted from the test material score in order to obtain the test material primary irritation score. The primary irritation score was calculated as indicated above and compared with the irritation response categories indicated in Table 3.

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Test Adı/Testing Name: **DERMAL İRRİTASYON & DERMAL IRRITATION**	Rapor Numarası/Report No	**KBYU0005/2021-03/BYU/1451**	

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Table 1: Weight table of tested test animals

Rabbit number	1	2	3
Weight at the beginning of the test*	2,376	2,361	2,387
Weight at end of test	2,376	2,361	2,387

*2,2-5 kg must be

TABLE 2: Scoring system for skin reaction

Reaction	Primary irritation scoring
Erythema and eschar formation	
No erythema	0
Very light erythema	1
Apparent erythema	2
Reasonable erythema	3
Serious erythema (like beet) and scar formation that prevents the grading of erythema	4
Edema formation	
No edema	0
Very light edema	1
Apparent edema (moderate)	2
Moderate edema (approximate 1 mm bloated)	3
Serious edema (Swollen more than 1 mm and spread out of the exposed alanine)	4
Total possible score for irritation	8
Other adverse changes in skin locations should be recorded and reported. .	

TABLE 3: Primary or Cumulative Irritation Index Categories

Average score	Answer category
0 - 0,4	Negligible
0,5 - 1,9	Mild
2 - 4,9	Medium
5 – 8	Serious

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TABLE 4: Evaluation Results

Rabbit No	Samples	Region	Observation (Hours)							
			Erythem				Edema			
			1.	24.	48.	72.	1.	24.	48.	72.
1	SPECIMEN	*left anterior region*	0	0	0	0	0	0	0	0
		right back region	1	1	1	0	0	0	0	0
	Positive Control	*right anterior region*	2	1	1	1	1	0	0	0
	Negative Control	*Left back region*	0	0	0	0	0	0	0	0
2	SPECIMEN	*left anterior region*	0	0	0	0	0	0	0	0
		right back region	1	1	0	0	0	0	0	0
	Positive Control	*right anterior region*	2	2	1	1	1	1	0	0
	Negative Control	*Left back region*	0	1	0	0	0	0	0	0
3	SPECIMEN	*left anterior region*	0	0	0	0	0	0	0	0
		right back region	1	1	1	0	0	0	0	0
	Positive Control	*right anterior region*	1	1	1	0	0	0	0	0
	Negative Control	*Left back region*	0	0	0	0	0	0	0	0

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TEST RESULT INFORMATION

TABLE 6: Average Score Value

Samples	Primary Irritation Score *			Primary Irritation Index
	Rabbit 1	Rabbit 2	Rabbit 3	
SPECIMEN	0,167	0,083	0,167	0,139
Positive Control	0,500	0,833	0,333	0,556
Negative Control	0,000	0,167	0,000	0,056

* 1. Hours are not taken into account when calculating the primary irritation score.

The sample was found to have no dermal irritation with a score of 0,139-0,056=0,083

7. EVALUATION

The average score was obtained by taking the average of the values obtained after the observation in four different time intervals after the test performed in accordance with TS EN ISO 10993-10 standards. Redness and edema were observed in the positive control, it was stated that there was no reaction in the test specimen and negative controls.

8.RESULT

Dermal İritasyon testinin ardından elde edilen sonuçlar doğrultusunda, ISO 10993-10 belgesinde belirtilen protokol ve değerlendirme kriterleri esas alındığında DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş firmasının, DEXXON MEDICAL DXNMD-NRFMO4 FFP2 NR lot numaralı, FFP2 NR DISPOSABLE VALVE FACE MASK numunesinin dermal iritan özelliğe sahip olmadığı tespit edilmiştir.

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9.RECORDS

All crude data, forms and a copy of the final report related to the test performed are stored in TECHCERT archive files.

10.REFERENCES

- Guide For The Care And Use Of Laboratory Animals Eighth Edition National Research Council of The National Academies
- TS EN ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing in a risk management process
- TS EN ISO 10993-2 Biological evaluation of medical devices - Part 2: Requirements for animal welfare
- TS EN ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitivity
- TS EN ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

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FİRMA ADI/COMPANY NAME:	**DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.**
ADRES/ADDRESS:	**İSTANBUL VİZYON PARK OFİS BLOKLARI YENİBOSNA MERKEZ MAH. 29 EKİM CAD. NO:3 PLAZA 1 K:8 NO:84 BAHÇELİEVLER – İSTANBUL - TURKEY**
TESTİN ADI/TESTING NAME:	**SENSİTİZASYON & SENSITIZATION**
TEST STANDARDI/TEST STANDARD:	**TS EN ISO 10993-10: 2014-02**
TİCARİ MARKA (VARSA)/COMMERCIAL BRAND (IF YOU HAVE):	**-**
ÜRÜN ADI/PRODUCT NAME:	**FFP2 NR DISPOSABLE VALVE FACE MASK**
NUMUNE KAYIT NO/SAMPLE REGİSTRATİON NO:	**KBYU0014/2021**
NUMUNE LOT NUMARASI/LOT NUMBER OF SPECIMENS:	**DEXXON MEDICAL DXNMD-NRFM04 FFP2 NR**
NUMUNE SAYISI/NUMBER OF SPECIMEN:	**6**
TEST BAŞLAMA TARİHİ/TEST START DATE:	**02.02.2021**
TEST BİTİŞ TARİHİ/TEST END DATE:	**02.03.2021**
RAPOR TARİHİ/REPORT DATE:	**22.03.2021**
KULLANILAN CİHAZLAR/USED DEVICES:	**-**
EA TANIMLAMASI/EA DESCRIPTION:	**Asia Pasific Accreditation Association (APAC) ISO/IEC 17025: 2017 CABs National Accreditation Center (NAC) by accredited the general requirements for the adequacy of the test and calibration laboratoires standard for the recognition of test report. It proves the traceability to national measurement standards that are defined in the International System of Units (SI), realizing the units.**

BİYOUYUMLULUK TEST SORUMLUSU **BİYOKİMYAGER** **YEŞİM ÖZKUL**	**VETERİNER HEKİM** **SONER AKTEMUR**	**TECHNICAL UNIVERSAL VERIFICATION**

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SENSITIZATION TEST RESULT REPORT

NAME OF TEST

ISO 10993-10 STANDARD

SENSITIZATION TEST

TEST REQUESTED INSTITUTION AND SPECIMEN NAME

DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.

FFP2 NR DISPOSABLE VALVE FACE MASK

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BİYOUYUMLULUK TEST LABORATUVARI
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1.GENERAL INFORMATION ABOUT THE TEST

Test Name and Guide	TS EN ISO 10993-10:2014 Biological evaluation of medical devices Chapter 10: Standard for test for irritation and skin sensitivity
Test Requesting Institution	**DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.**
Test Report Number	KBYU0005/2021-03/BYU/1450
Test Start Date	**02.02.2021**
Test Ending Date	**02.03.2021**
Test Reporting Date	**22.03.2021**
Purpose	The test is intended to assess the sensitizing potential of the specimen described below

2.INFORMATION ABOUT THE SPECIMEN

Sample Acceptance Date and Time	28.01.2021
Sample Registration Number	KBYU0014/2021
Sample Lot Number	DEXXON MEDICAL DXNMD-NRFMO4 FFP2 NR
Sample Name	FFP2 NR TEK KULLANIMLIK VALFSİZ YÜZ MASKESİ
Number of Samples	6
Status at the Time of Sampling	KATI / SOLID
Delivery Method of the Sample	HAND BY RECEİVE
Witness Sample Information	Preserve TECHCERT laboratory for 1 year

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3.INFORMATION ABOUT THE TEST ANIMALS TAKEN IN THE TEST

Kind	Guinea Pig
Family	Dunkin Hartley
Source	Kobay DHL A.Ş.
Gender	Male
Weight Source	400-500 gr
Age	10-12 week
Familiarization Period	5 days
Number of Animals Used	15 pieces

4. INFORMATION ABOUT LABORATORY CONDITIONS

Test Animal Maintanence	The animal used in the tests are made in accordance with the Biological Evaluation of Medical Devices-Part 2 Requirements for Animal Welfare standards.
Forage	Ad-libitum is done feeding.
Water	Water, be given ad-libitum as suitable drinkers.
Micro Maintanence Conditions	Each test animal was identified and placed in appropriate cages.
Macro Maintanence Conditions	Provides 12 hours of night and 12 hours of daytime environment; %30-70 damp and 23 ºC environment is provided. temperature and damp are checked instant daily.
Test Team	Tests are carried out by trained and suitably qualified people
Selection of Test Animals	Healthy, disease-free and under the supervision of a veterinarian it was selected by passing.

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5. INFORMATION ABOUT THE TEST METHOD

Sensitization Tests; TS EN ISO 10993-10 Biological Evalaulation of Medical Devices-Chapter 10: According to the requirements of the test standard for irritation and skin sensitivity, the maintanence conditions of the test animals used in the test were carried out by considering ISO 10993-2 and the preparation of the specimen used in the test and the reference materials ISO-10993-12 standards.
Sensitization Tests; Intradermal Induction Phase, Superfical Induction Phase and subsequently the Stimulation Phase, observing the animals and evaluating finished the results.

6.TEST

Test start date	02.02.2021
Test ending date	02.03.2021
TS EN ISO 10993-10 Biological Evaluation of Medical Devices – Chapter 10: Biocompatibility test was applied according to the test standard for irritation and skin sensitivity. Animals TS EN 10993-2:2006 Biological Evaluation of Medical Devices – Chapter 2: It has been prepared in accordance with the principles of Requirements for Animal Welfare. The test was carried out in order to evaluate the sensitizing potential of the specimen	
Solution preparation date	31.01.2021 – 02.02.2021
Solution preparation know how	Chapter 12: According to specimen preparation and reference materials standard; ☒ If specimen solid; "The specimen was prepared by keeping the specimen at 37°C for 72 hours according to the chart of standard surface areas and extract liquid volumes. Subsequently, it was impregnated with a 25x25 mm four-layer gauze and applied to the skin. ☐ If specimen liquid; directly impregnated with 25x25 mm four-layer gauze and applied to the skin. Serum Physiological impregnated with 25x25 mm four-layer gauze was used as a control specimen.

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CRANIAL TIP

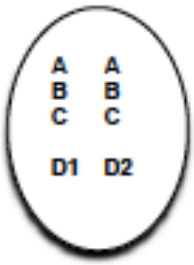

Figure 1 – Test Group

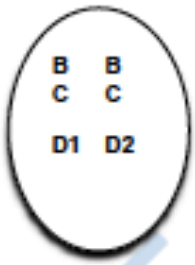

Figure 2 – Control Group

CAUDAL TIP

Table 1: Weight table at the end of the test belonging to the test animals

TEST GROUP Guinea pig no	1	2	3	4	5	6	7	8	9	10
Weights at the begenning of the test*	487	458	472	489	466	477	433	441	452	473
Weights at the end of the test	489	481	488	484	484	508	483	473	483	507
CONTROL GROUP Guinea pig no	1		2		3		4		5	
Weights at the begenning of the test*	458		450		483		488		446	
Weights at the end of the test	483		478		482		494		478	

*300-500gr must be

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Table 2: Magnusson and Kligman rating scale

Patch Test Reaction	Rating Scale
No Visible Change	0
Discrete or Patchy erthema	1
Moderate or Adjacent Erythema	2
Apparent	3
Serious Erythema or Swelling	4

Table 3: Results obtained in 24 and 48 hours of test and control groups based on the Magnusson and Kligman rating scale

	GUINEA PIG NO	ZONE	MAGNUSSON AND KLIGMAN RATING ERYTHEMA / EDEMA EVALUATION HOUR	
			24TH HOURS	48TH HOURS
TEST GROUP	1	A	3	3
		B	0	1
		C	0	1
		D1	1	0
		D2	0	0
	2	A	2	3
		B	1	1
		C	1	1
		D1	1	0
		D2	0	0
	3	A	2	2
		B	0	0
		C	0	1
		D1	1	0
		D2	1	0
	4	A	4	2
		B	1	0

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		C	0	0
		D1	0	0
		D2	1	0
	5	A	3	2
		B	1	0
		C	1	1
		D1	0	0
		D2	0	0
	6	A	3	3
		B	1	1
		C	2	0
		D1	0	1
		D2	1	0
	7	A	4	3
		B	1	0
		C	0	0
		D1	1	0
		D2	0	0
	8	A	2	2
		B	1	1
		C	0	0
		D1	0	0
		D2	0	0
	9	A	2	3
		B	1	1
		C	1	1
		D1	0	0
		D2	0	0
	10	A	3	4

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		B	1	1
		C	0	1
		D1	0	0
		D2	0	0
CONTROL GROUP	1	A	-	-
		B	2	0
		C	1	1
		D1	0	0
		D2	0	0
	2	A	-	-
		B	1	2
		C	1	1
		D1	0	1
		D2	0	0
	3	A	-	-
		B	0	0
		C	2	1
		D1	0	0
		D2	0	0
	4	A	-	-
		B	1	0
		C	0	0
		D1	0	0
		D2	1	1
	5	A	-	-
		B	1	1
		C	1	1
		D1	0	0
		D2	0	0

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Table 4: Group-based average of observed results

Groups	Average Results
Test Group	0,88
Control Group	0,50

7. INTRA SKIN INDUCING PHASE

Intradermal applications in the regions and volumes indicated in figures 1 and 2 were applied to guinea pigs in the test and control groups.

INTRADERMAL INDUCING PHASE

0.1 ml intradermal applications were made with the below contents.

TEST GROUP:

Figure 1 Region A: FCA at 50:50 volume at the rate of (Freund's Complete Adjuvant) and Saline Solution.

Figure 1 Region B: Specimen extract (undiluted extract).

Figure 1 Region C: Mixtures of materials applied in regions A and B in a 50:50 volume at the rate of.

Figure 1 Region D1 ve D2: Topical application areas.

KONTROL GRUBU:

Figure 2 Region A: -

Figure 2 Region B: Saline Solution

Figure 2 Region C: FCA at 50:50 volume at the rate of (Freund's Complete Adjuvant) and Saline Solution.

Figure 2 Region D1 ve D2: Topical application areas.

Intra-Skin Induction Start Date	02.02.2021
Intra-Skin Induction End Date	09.02.2021

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8. SURFACE (TOPICAL) INDUCING PHASE

On the 7th day after the completion of the intradermal induction phase; Superficial application has been made to the areas specified in Figures 1 and 2. The area is covered with gauze and all application areas are wrapped with an elastic bandage. The bandage and patches were removed after 48 hours.

SURFACE (TOPICAL) INDUCING PHASE

On the 7th day after the completion of the intradermal induction phase;

A superficial application is made to the intrascapular area (Figure1-D1) with 8 square centimetre absorbent gauze to the TEST GROUP. The area is covered with gauze, all application areas are wrapped with an elastic bandage. In the Intradermal Induction Phase, the concentration determined in Test Group Zone B is used.

CONTROL GROUP; (Figure2- D1) saline solution is used only. The area is covered with gauze, all application areas are wrapped with an elastic bandage. Bandages and patches removed after 48 hours.

Superficial Induction Phase start date	09.02.2021
Superficial Induction Phase end date	23.02.2021

9.STIMULATION PHASE

On the 14th day after the completion of the surface induction phase; Superficial application has been made to the areas specified in Figures 1 and 2. The area is covered with gauze and all application areas are wrapped with an elastic bandage. The bandage and patches were removed after 48 hours.

Technical Universal Verification	TECHNICAL UNIVERSAL VERIFICATION BELGELENDİRME VE EĞİTİM HİZ. LTD. ŞTİ. Macun Mahallesi ATB İş Merkezi A Blok No: 3 Yenimahalle / ANKARA Tel: +90 312 231 82 02 & E-Mail. info@techcert.com.tr & www.techcert.com.tr		NAC NAC-003-TL
Test Adı/Testing Name: SENSİTİZASYON & SENSITIZATION	Rapor Numarası/Report No	KBYU0005/2021-03/BYU/1450	

** This report ISO 17025: has been prepared within the scope o general conditions for the competence of testing and calibration laboratories

BİYOUYUMLULUK TEST LABORATUVARI
BIOCOMPATIBILITY TESTING LABORATORY

STIMULATION PHASE	
On the 14th day after the completion of the surface induction phase;	
TEST GROUP; Superficial treatment is applied to untreated areas of experimental animals (Figure 1 D2). The area is covered with gauze, all application areas are wrapped with an elastic bandage. In the Intradermal Induction Phase, the concentration determined in Test Group Zone C is used. CONTROL GROUP; (Figure2- D2) saline solution is used only. The area is covered with gauze, all application areas are wrapped with an elastic bandage. Bandages and patches removed after 48 hours.	
Stimulation Phase Start Date	23.02.2021
Stimulation Phase End Date	02.03.2021

10.RESULT

In line with the results obtained after the sensitization test, based on the protocol and evaluation criteria specified in the ISO 10993-10 document, **DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.** It was determined that the **FFP2 NR DISPOSABLE VALVE FACE MASK** specimen with -- **DEXXON MEDICAL DXNMD-NRFMO4 FFP2 NR** lot number was not sensitizing.

11.RECORDS

All crude data, forms and a copy of the final report related to the test performed are stored in TECHCERT archive files.

12.REFERENCES

- Guide For The Care And Use Of Laboratory Animals Eighth Edition National Research Council of The National Academies
- TS EN ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing in a risk management process
- TS EN ISO 10993-2 Biological evaluation of medical devices - Part 2: Requirements for animal welfare
- TS EN ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitivity
- TS EN ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

BIOCOMPABILITY TESTS : DERMAL IRRITATION TEST ANALYSIS

KOBAY deney hayvanları laboratuvarı

SAMPLE NO: KBYU0014/2021

KOBAY DENEY HAYVANLARI LABORATUVARI SAN. VE TİC. A.Ş. DERMAL IRRITATION TEST ANALYSIS FORM	
Test Name	TS EN ISO 10993-10 Biological evaluation of medical devices Chapter 10: Standard of experiments for irritation and skin sensitivity
Test Start Date	02.03.2021
Test End Date	05.03.2021

Biocompatibility test has been applied according to TS EN ISO 10993-10 Biological evaluation of medical devices - Part 10: Experiments for irritation and skin sensitivity. Animals have been prepared in accordance with the principles of TS EN 10993-2: 2006 Biological Evaluation of Medical Devices - Part 2: Requirements for Animal Welfare. The test was carried out in order to evaluate the sensitizing potential of the sample.

Solution Preparation Date	28.02.2021
Prepare a solution technical knowledge	Chapter 12: According to the standard of sample preparation and reference materials; • If the sample is solid; "According to the standard surface areas and extract liquid volumes chart, the sample was prepared by holding for 37°C for 72 hours. Then 25x25 mm was absorbed into four-layer gauze and applied to the skin ○ If the sample is liquid; directly absorbed into 25x25 mm four-layer gauze and applied to the skin, 25x25 mm four-layer gauze-absorbed Saline was used as a control sample

CRANIAL END

Figure I

CAUDAL END

DERMAL APPLICATION

The samples were applied as shown in Figure 1 after shaving the experimental animals (their weights are recorded in Table 1) one day before the application to provide sufficient application area (10 cm x 15 cm) in the back area. After covering the samples with 2.5 cm x 2.5 cm sterile gauze, the entire application area was wrapped with a bandage. The samples to be tested for 4 hours were applied to the area. At the end of this period, bandages were opened, samples were taken and the applied areas were marked. Test materials remaining in the area were washed with warm water.

Figure 1 Zone 1: Sample
Figure 1 Zone 2: Positive Control
Figure 1 Zone 3: Negative Kontrol
Figure 1 Zone 4: Sample

Dermal Application start date and time	02.03.2021 11:45
Dermal Application end date and time	02.03.2021 15:45

KBY_F_34_10 / R00

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SAMPLE N0:
KBYU0014/2021

After the process, the test zones were observed at the 1st, 24th, 48th and 72nd hours and samples were evaluated considering the criteria specified in Table 2. Observations 72 hours after administration were not taken into account. All erythema and edema scores were collected separately for each sample at 24, 48 and 72nd hours in each rabbit. The primary irritation score for a rabbit was calculated by dividing all scores by six. The primary irritation index for the test sample was calculated by dividing the sum of each animal's primary irritation index by three. Primary irritation was also calculated for the controls. This score is subtracted from the test material score in order to obtain the test material primary irritation score. The primary irritation score was calculated as indicated above and compared with the irritation response categories indicated in Table 3.

Table 1: Weight table of experimental animals taken to the test

Rabbit No	1	2	3
Weights at Test Start*	2,376	2,361	2,387
Weights at The End of the Test	2,376	2,361	2,387

*Must be between 2-2,5 kgs.

Table 2: Score system for skin reaction

Reaction	Primary Irritation Score
Erythema and eschar formation	
No erythema	0
Very light erythema (barely visible)	1
Pronounced erythema	2
Moderate erythema	3
Between severe erythema (beetroot red) and eschar formation that prevents erythema from grading	4
Edema formation	
No erythema	0
Very light erythema	1
Prominent edema (marked edema edges to the area)	2
Moderate edema (about 1 mm raised)	3
Severe edema (swollen more than 1 mm and spread beyond the exposed area)	4
Total possible score for irritation	8
Other adverse changes in skin locations should be recorded and reported.	

Table 3: Primary or Cumulative Irritation Index Categories

Average Score	Answer Category
0 - 0,4	Negligible
0,5 - 1,9	Light
2 - 4,9	Moderate
5 – 8	Severe

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SAMPLE N0:
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Table 4: Evaluation Results

Rabbit No.	Samples	Zone	Observation (Hrs.)							
			Rash				Edema			
			1.	24.	48.	72.	1.	24.	48.	72.
1	SAMPLE	*Left Front Area*	0	0	0	0	0	0	0	0
		Right Back Area	1	1	1	0	0	0	0	0
	Positive Control	*Right Front Area*	2	1	1	1	1	0	0	0
	Negative Control	*Left Back Area*	0	0	0	0	0	0	0	0
2	SAMPLE	*Left Front Area*	0	0	0	0	0	0	0	0
		Right Back Area	1	1	0	0	0	0	0	0
	Positive Control	*Right Front Area*	2	2	1	1	1	1	0	0
	Negative Control	*Left Back Area*	0	1	0	0	0	0	0	0
3	SAMPLE	*Left Front Area*	0	0	0	0	0	0	0	0
		Right Back Area	1	1	1	0	0	0	0	0
	Positive Control	*Right Front Area*	1	1	1	0	0	0	0	0
	Negative Control	*Left Back Area*	0	0	0	0	0	0	0	0

TEST RESULT INFORMATION

Table 5: Average Score Value

SAMPLES	Primary Irritation Score*			Primary Irritation Index
	Rabbit 1	Rabbit 2	Rabbit 3	
SAMPLE	0,167	0,083	0,167	0,139
Positive Control	0,500	0,833	0,333	0,556
Negative Control	0,000	0,167	0,000	0,056

* 1st Hours are not considered when calculating the primary irritation score.

It was determined that the sample did not have dermal irritation feature with an irritation score of 0.139-0.056 = 0.083.

SIGNATURES OF THE RESPONSIBLE PERFORMANCE OF THE TEST	BYU 3	BYU 5
	e- signed	e- signed

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KOBAY DENEY HAYVANLARI LABORATUARI SAN. VE TİC. A.Ş.
DERMAL IRRITATION TEST ANALYSIS FORM

Test Report Number: KBYU0014/2021-602.000.0042

4. INFORMATION ABOUT LABORATORY CONDITIONS

Care of Experimental Animals	The animals used in the experiments are made in accordance with the Biological Evaluation of Medical Devices-Part 2: Requirements for Animal Welfare standards.
Feed	Ad-libitum feeding is performed.
Water	Water is given in suitable waters as ad-libitum.
Micro Care Conditions	Each experimental animal was identified and placed in appropriate cages.
Macro Care Conditions	The environment is provided for 12 hours at night and 12 hours during the day; 30-70% humidity and 17-23 °C environment are provided. Temperature and humidity are instantly controlled daily.
Test Study Team	Tests are carried out by trained and qualified persons.
Experimental Animal Selection	They were selected as healthy, without any disease and under the supervision of a veterinarian.

5. INFORMATION ABOUT THE TEST METHOD

Dermal irritation tests; TS EN ISO 10993-10 Biological evaluation of medical devices - Part 10: According to the requirements of the experiments standard for irritation and skin sensitivity, the maintenance conditions of the test animals used in the test, ISO 10993-2 and the preparation of the samples used in the test and the reference materials taking into account the ISO-10993-12 standards has been carried out.

Dermal Irritation Tests; Following the skin application, the animals were observed at different time intervals and the results were evaluated.

6. DERMAL APPLICATION

Samples are prepared according to the "Standard surface areas and extract liquid volumes chart" in the standard of TS EN ISO 10993-12 "Sample Preparation and Reference Materials". (KBY_F_24_10) As Positive Control; Sodium lauryl sulfate (SLS), previously known to have an irritant effect, has been determined. As Negative Control; Saline Solution, previously known to have no irritant effect, was determined.
The test and control samples of the test animals, whose weights were recorded in Table 1 in KBY_F_24_10, were topically applied to the skin in the regions and volumes indicated in Figure 1 in KBY_F_24_10 for 4 hours. At the end of this period, bandages were opened, samples were taken, and the applied areas were marked. Test materials remaining in the area were washed with warm water. After the procedure, the test zones were observed at the 1st, 24th, 48th and 72nd hours and samples were evaluated by considering the criteria in Table 2 in KBY_F_24_10. The evaluation results that should be given according to the points obtained are recorded in Table 3 in KBY_F_24_10.

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KOBAY DENEY HAYVANLARI LABORATUARI SAN. VE TİC. A.Ş.
DERMAL IRRITATION TEST ANALYSIS FORM

Test Report Number: KBYU0014/2021-602.000.0042

7. EVALUATION

The average score was obtained by taking the average of the values obtained after the observation in four different time intervals after the experiment performed in accordance with TS EN ISO 10993-10 standards. Redness and edema were observed in the positive control, it was stated that there was no reaction in the test sample and negative controls. Obtained (evaluation criteria and records are included in Tables 4 and 5 in KBY_F_24_10).

8. RESULT

In line with the results obtained after the dermal irritation test, based on the protocol and evaluation criteria specified in the ISO 10993-10 document, it was determined that the received_ institution, lot number lot number, sample_name sample did not have dermal irritant properties.

9. RECORD

All raw data, forms (KBY_F_24_10) and a copy of the final report related to the test are kept in the archive files of Kobay DHL A.Ş.

10. REFERENCE

- Guide For The Care And Use Of Laboratory Animals Eighth Edition National Research Council of The National Academies
- TS EN ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing in a risk management process
- TS EN ISO 10993-2 Biological evaluation of medical devices - Part 2: Requirements for animal welfare
- TS EN ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitivity
- TS EN ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

11. SIGNATURES OF THE RESPONSIBLE PERFORMANCE OF THE TEST

BYU 3	BYU 5
e- signed	e- signed

BIOCOMPABILITY TESTS: SENSITIZATION TESR RESULT REPORT

KOBAY DENEY HAYVANLARI LABORATUARI SAN. VE TİC. A.Ş.
SENSITIZATION TEST RESULT REPORT

Test Report Number: KBYU0014/2021-602.000.0011

1. GENERAL INFORMATION ABOUT THE TEST	
Test Name and Guide	TS EN ISO 10993-10: 2014 Biological evaluation of medical devices Part 10: Tests standard for irritation and skin sensitivity
Requesting Institution	DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş
Test Report Number	KBYU0014/2021-602.000.0011
Test Start Date	02.02.2021
Test End Date	02.03.2021
Test Raporlandırma Tarihi	02.03.2021
Information About Test Responsible	The tests were carried out in the laboratory of KOBAY DHL A.Ş by the persons whose full names were specified in the ethics committee approval with the ethics board dated 02.01.2020 and ethical board number 525.
Objective	The test is intended to assess the sensitizing potential of the sample described below.
2. INFORMATION ABOUT THE SAMPLE	
Sample Acceptance Date - Time	28.01.2021
Sample Registration Number	KBYU0014/2021
Sample Lot Number	DEXXON MEDICAL DXNMD-NRFMO4 FFP2 NR
Sample Name	FFP2 NR TEK KULLANIMLIK VALFSİZ YÜZ MASKESİ
Number of Samples	6
Status at the Time of Sampling	KATI / SOLID
Delivery Method of the Sample	KARGO / CARGO
Sample Production Date	
Sample Expiry Date	
Witness Sample Information	It is stored in the laboratory of KOBAY DHL A.Ş for 1 year.
3. INFORMATION ABOUT EXPERIMENTAL ANIMALS TAKEN IN THE TEST	
Type	Guinea Pig
Strain	Dunkin Hartley
Source	Kobay DHL A.Ş.
Gender	Male
Weight Range	400-500 gr
Age	10-12 weeks
Familiarization Period	5 days
Number of Animals Used	15

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KOBAY DENEY HAYVANLARI LABORATUARI SAN. VE TİC. A.Ş.
SENSITIZATION TEST RESULT REPORT

Test Report Number: KBYU0014/2021-602.000.0011

4. INFORMATION ABOUT THE TEST METHOD

Care of Experimental Animals	The animals used in the experiments are made in accordance with the Biological Evaluation of Medical Devices-Part 2: Requirements for Animal Welfare standards.
Feed	Ad-libitum feeding is performed.
Wate	Water is given in suitable waters as ad-libitum.
Micro Care Conditions	Each experimental animal is identified and placed in the appropriate cages
Macro Care Conditions	The environment is provided for 12 hours at night and 12 hours during the day; 30-70% humidity and 22-24 ºC environment are provided. Temperature and humidity are instantly controlled daily.
Test Study Team	Tests are carried out by trained and suitably qualified people.
Experimental Animal Selection	They were selected as healthy, without any disease and under the supervision of a veterinarian.

5. INFORMATION ABOUT THE TEST METHOD

Sensitization Tests; TS EN ISO 10993-10 Biological evaluation of medical devices - Part 10: According to the requirements of the experiments standard for irritation and skin sensitivity, the maintenance conditions of the test animals used in the test, ISO 10993-2 and the preparation of the samples used in the test and the reference materials taking into account the ISO-10993-12 standards has been carried out.

Sensitization Tests; Following the Transcutaneous Induction Phase, Superficial Induction Phase and Stimulation Phase, the animals were observed, and the results were evaluated.

6. Intra-Skin Induction Phase

Intradermal applications in the regions and volumes specified in Figures 1 and 2 in KBY_F_24_02 were applied to guinea pigs in test and control groups.

7. Superficial (Topical) Induction Phase

On the 7th day after the completion of the intradermal induction phase; in KBY_F_24_02, superficial application has been made to the regions specified in Figures 1 and 2. The area is covered with gauze and all application areas are wrapped with an elastic bandage. The dressing and patches were removed after 48 hours.

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KOBAY DENEY HAYVANLARI LABORATUARI SAN. VE TİC. A.Ş.
SENSITIZATION TEST RESULT REPORT

Test Report Number: KBYU0014/2021-602.000.0011

8. STIMULATION PHASE

On the 14th day after the completion of the superficial induction phase; in KBY_F_24_02, superficial application has been made to the regions specified in Figures 1 and 2. The area is covered with gauze and all application areas are wrapped with an elastic bandage. The dressing and patches were removed after 48 hours.

9. EVALUATION

Stimulation sites on the skin of animals in the test and control groups are observed 24 hours and 48 hours after the completion of the stimulation phase. Observations are carried out under full spectrum lighting. Skin reactions for Erythema and Edema are completed and graded according to the Magnusson and Kligman grading at each time interval for each stimulation site. The weight values of guinea pigs have been recorded. (evaluation criteria and records are in KBY_F_24_02).

10. RESULT

In line with the results obtained after the sensitization test, based on the protocol and evaluation criteria specified in the ISO 10993-10 document, it was determined that the DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş , DEXXON MEDICAL DXNMD-NRFMO4 FFP2 NR, FFP2 NR TEK KULLANIMLIK VALFSİZ YÜZ MASKESİ sample did not have sensitizing properties.

11. RECORD

All raw data, forms (KBY_F_24_02) and a copy of the final report related to the test are kept in the archive files of Kobay DHL A.Ş.

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KOBAY

KOBAY DENEY HAYVANLARI LABORATUARI SAN. VE TİC. A.Ş.
SENSITIZATION TEST RESULT REPORT

Test Report Number: KBYU0014/2021-602.000.0011

12. REFERENCE

- Guide For The Care And Use Of Laboratory Animals Eighth Edition National Research Council of The National Academies
- TS EN ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing in a risk management process
- TS EN ISO 10993-2 Biological evaluation of medical devices - Part 2: Requirements for animal welfare
- TS EN ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitivity
- TS EN ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

13. SIGNATURES OF THOSE RESPONSIBLE FOR PERFORMING THE TEST

BYU 3	BYU 5
e- signed	e- signed