UNIVERSAL CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD - 104

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Economic Commission directive 93/68/EEC amending Medical Devices Directive dated 22 July 1993,

the products manufactured for

DISTRIBUZIONE JUNIOR SRL
Via Pace, 25/26 - 80047 San Giuseppe Vesuviano (Na) ITALY
Manufactured at
XIANTAO CITY CANCAN NONWOVEN PRODUCTS CO.,LTD
Group 3, San Wan Village, Sanfutan Town, Xiantao City Hubei Province CHINA
has been tested in accordance with the relevant articles of

EN 14683:2019+AC:2019 Medical Face Masks

Brand Name : ENHANCE
Model : EH3625
Type II
are tested according to the following initial type tests by the manufacturer

Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods

For the assessment of conformity, the following documents were also applied to:
Results of laboratory tests NP Testing Laboratory BFE
Results of laboratory tests NP Testing Laboratory Differential Pressure
Results of laboratory tests NP Testing Laboratory Microbial Cleanliness

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the medical face masks manufactured and designed for use during the medical operations or similar medical situations with same requirements which require restriction of infectious materials to be spread to patients. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; reference to EN 14683 standard, type of mask (as indicated in Table 1) and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 08/05/2020 and valid until 07/05/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

İSTANBUL –08/05/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Genel Müdür

Verify the validity with the QR Code

UNIVERSALCERT.COM

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

Test
TS EN ISO/IEC 17025
AB-0583-T

TEST REPORT
DENEY RAPORU

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20039086-ing
10-20

Customer name:	DISTRIBUZIONE JUNIOR SRL
Address:	25/6-80047 SAN GIUSEPPE VESUVIAO (NA)/ITALY
Buyer name:	MEGACERT ULUSLARARASI BELGELENDİRME VE EĞİTİM HİZ. LTD. ŞTİ.
Contact Person:	-
Order No:	19
Article No:	ADULT MASK EH3625
Name and identity of test item:	Blue non-woven mask .(Claimed to be Colour code: Blue)
The date of receipt of test item:	19.10.2020
Re-submitted/re-confirmation date:	-
Date of test:	19.10.2020-26.10.2020
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	Not Specified
Number of pages of the report:	5

The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 as test laboratory.
The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

Seal	**Date**	**Customer Representative**	**Head of Testing Laboratory**
	26.10.2020	Ahmet ÇİRKİN	Sevim A. RAZAK 26.10.2020

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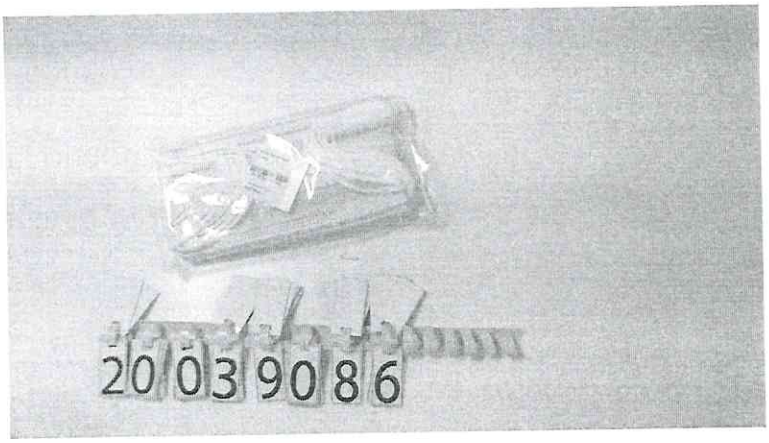
REQUIRED TESTS	RESULT	COMMENTS
ECOLOGICAL TESTS		
Forbidden Arylamines In Dyestuff	P	
Chromium VI	P	

P: Pass
F: Fail
R: Refer to retailer technologist.
Test results were evaluated according to "Registration, Evaluation, Authorisation and Restriction of Chemicals" Legislation limit values dated on 23.06.2017 and No: 30105.

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified. If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95 %. The declaration of conformity was given in accordance with the Simple Acceptance Decision RuleTests marked (*) in this report are not included in the accreditation schedule.



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TEST RESULTS

FORBIDDEN AROMATIC ARYLAMINES-MAK III GROUP A1&A2 CATEGORY

Corresponding to the Ordinance on Commodities (Bedarfsgegenständeverordnung) be in force respectively the directive 2002/61/EEC the use of certain azo colorants is banned, which can release by reductive cleavage of their azo group(s) one or more of certain listed aromatic and cancerogenic amines.

Arylamines of class MAK III A1/ A2 are determined and quantified using a Gas Chromatography / Mass Selective Detector (GC/MSD)

List of arylamines,that are not allowed to be split off from dyes under reductive conditions ;

Nr	Substances	CAS No	Index No	EC number
	MAK III A1			
01	4-Aminobiphenyl	92-67-1	612-072-00-6	202-177-1
02	Benzidine	92-87-5	612-042-00-2	202-199-1
03	4-Chloro-o-toluidine	95-69-2		202-441-6
04	2-Naphthylamine (-Naphthylamine)	91-59-8	612-022-00-3	202-080-4
	MAK III A2			
05*	o-Aminoazotoluol (4-amino-2,3-dimethylazobenzene)	97-56-3	611-006-00-3	202-591-2
06	p-Chloroaniline (4-chloroaniline)	106-47-8	612-137-00-9	203-401-0
07	2,4-Diaminoanisole (4-Methoxy-m-phenylenediamine)	615-05-4		210-406-1
08	4,4'-Diaminodiphenylmethane (4,4'-methylendianiline)	101-77-9	612-051-00-1	202-974-4
09	3,3'-Dichlorbenzidine (3,3'-dichlorobiphenyl-4,4'-xylendiamine)	91-94-1	612-068-00-4	202-109-0
10	3,3'-Dimethoxybenzidine (o-Dianisidine)	119-90-4	612-036-00-X	204-355-4
11	3,3'-Dimethylbenzidine (o-Tolidine) (4,4'-bi-o-toluidine)	119-93-7	612-041-00-7	204-358-0
12	3,3'-Dimethyl-4,4'-diaminodiphenylmethane (4,4'-methylene di-o-toluidine)	838-88-0	612-085-00-7	212-658-8
13	4,4'-Methylene-bis-(2-chloro-aniline) (2,2'-dichloro-4,4'-methylenedianiline)	101-14-4	612-078-00-9	202-918-9
14*	2-Amino-4-nitrotoluene (5-nitro-o-toluidine)	99-55-8		202-765-8
15	4,4'-Oxydianiline (4,4'-Diaminodiphenylether)	101-80-4		202-977-0
16	4,4'-Thiodianiline (4,4'-Diaminodiphenylsulfide)	139-65-1		205-370-9
17	o-Toluidine (2-aminotoluene)	95-53-4	612-091-00-X	202-429-0
18	4-Methyl-1,3-phenylendiamin (4-methyl-m-phenylendiamin) (2,4-Toluenediamine)	95-80-7	612-099-00-3	202-453-1
19	2,4,5-Trimethylaniline	137-17-7		205-282-0
20	o-Anisidine (2-Methoxyaniline)	90-04-0	612-035-00-4	201-963-1
21	2-Methoxy-5-methylaniline (p-Cresidine) (6-methoxy-m-toluidine)	120-71-8		204-419-1
22**	4-Amino Azobenzene	60-09-3	611-008-00-4	200-453-6
23***	2,4-Xylidine	95-68-1		
24***	2,6-Xylidine	87-62-7		

* The CAS-numbers 97-56-3 (No. 5) and 99-55-8 (No. 14) are detected further reduced to CAS-numbers 95-53-4 (No. 17) and 95-80-7 (No. 18).

** Azo colorants that are able to form 4-aminoazobenzene generate, under the condition of this method, aniline (CAS-number 62-53-3) and 1,4-phenylenediamine (CAS – number 106-50-3). Due to detection limits, only aniline may be detected. If aniline is detected above 5 mg/kg, then the presence of these colorants should be tested by ISO 14362-3 (for leathers ISO 17234-2).

*** Not regulated by law

Note: In case the sample was a blend of coloured synthetic material with further coloured fibers several test methods were carried out if necessary.

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TEST RESULTS

CHROMIUM VI : ISO 17075-2:2017

Leather sample is extracted with phosphate buffer solution (pH 7-8) . The amount of Chromium (VI) in the filtrated extract is determined by High Performance Liquid Chromatography.

RESULTS		
COMPONENT	CHROMIUM VI RESULTS(mg/kg)	EVALUATION
Blue main	N.D.	Pass

(1) N.D: Not detected

Leather articles cannot be marketed if they contain 3 mg / kg (0.0003% by weight) of chromium VI in excess weights.

ppm = part per million (mg/kg)
LS. : Lack of sample.

Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante:
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM: **1952605**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:05/07/2020

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	1952605	N	EH3625	MASCHERINA CHIRURGICA - TIPO II	T020601 - MASCHERINE CHIRURGICHE STANDARD	I - Classe I non sterile e senza funzioni di misura	14/05/2020		FABBRICANTE	XIANTAO CITY CANCAN NONWOVEN PRODUCTS CO.,LTD			CN
									MANDATARIO	DISTRIBUZIONE JUNIOR S.R.L.	08836731219	08836731219	IT

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