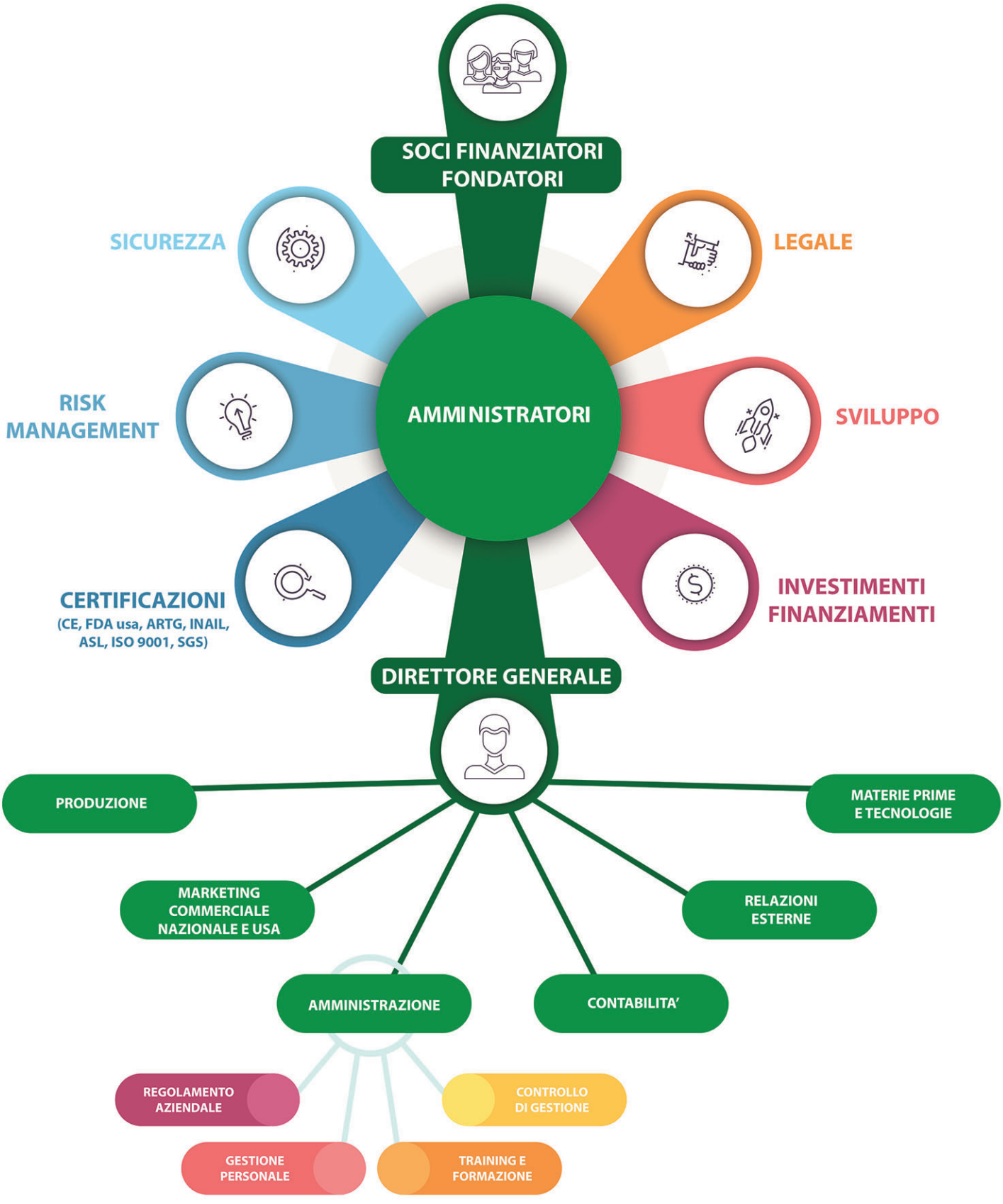
D.H.H.srl
SHIELD
MEDICAL SOLUTIONS

SHIELD MEDICAL SOLUTIONS

LA SOCIETÀ D.H.H. SRL NASCE NEL 2017 PER LA PRODUZIONE E LA VENDITA DI SISTEMI PER LA PREVENZIONE INDIVIDUALE. NELLO SPECIFICO CI OCCUPIAMO DI DISPOSITIVI DI PROTEZIONE INDIVIDUALE (MATERIALI DPI). IL NOSTRO CORE BUSINESS COMPRENDE LA PRODUZIONE DI MASCHERINE 3PLY PERSONALIZZABILI, 3PLY TIPO IIR MEDICHE CHIRURGICHE, FFP2 E FFP3.

D.H.H. LTD. IS A COMPANY, BORN IN 2017, BASED ON THE PRODUCTION AND SELLING OF PERSONAL PROTECTIVE EQUIPMENT (PPE). OUR CORE BUSINESS IS BASED ON THE PRODUCTION OF DIFFERENT TYPES OF FACE MASKS; WE PRODUCE CUSTOMISED 3PLY MASKS, 3PLY IIR SURGICAL MASKS, FFP2 AND FFP3 MASKS.

SHIELD MEDICAL SOLUTIONS



SHIELD WORLDWIDE

LE NOSTRE STRUTTURE SONO LOCALIZZATE IN DIVERSI PAESI DEL MONDO TRA CUI STATI UNITI, CINA E AUSTRALIA. IN ITALIA ATTUALMENTE LA NOSTRA SEDE OPERATIVA È SITUATA NELLA CITTÀ DI POMEZIA, IN PROVINCIA DI ROMA.

OUR FACILITIES ARE LOCATED IN SEVERAL COUNTRIES WORLDWIDE INCLUDING THE UNITED STATES, CHINA AND AUSTRALIA. IN ITALY, OUR OPERATIONAL HEADQUARTERS ARE CURRENTLY LOCATED IN THE CITY OF POMEZIA, IN THE PROVINCE OF ROME.

TECNOLOGIE INNOVATIVE

INNOVATIVE TECHNOLOGIES

LA NOSTRA MISSIONE È DI PRODURRE MASCHERINE DI ALTA QUALITÀ A LIVELLO GLOBALE E LOCALE, COMBINANDO LE NOSTRE TECNOLOGIE INNOVATIVE LEADER A LIVELLO MONDIALE E IL FOCUS SULLA QUALITÀ DEI NOSTRI PRODOTTI APPREZZATI DA CLIENTI IN TUTTO IL MONDO.

OUR MISSION IS TO PRODUCE HIGH QUALITY MASKS GLOBALLY AND LOCALLY, COMBINING OUR LEADING INNOVATIVE TECHNOLOGIES AND THE FOCUS ON THE QUALITY OF OUR PRODUCTS APPRECIATED BY CUSTOMERS WORLDWIDE.

CAMERA BIANCA

STERILE CLEANROOM

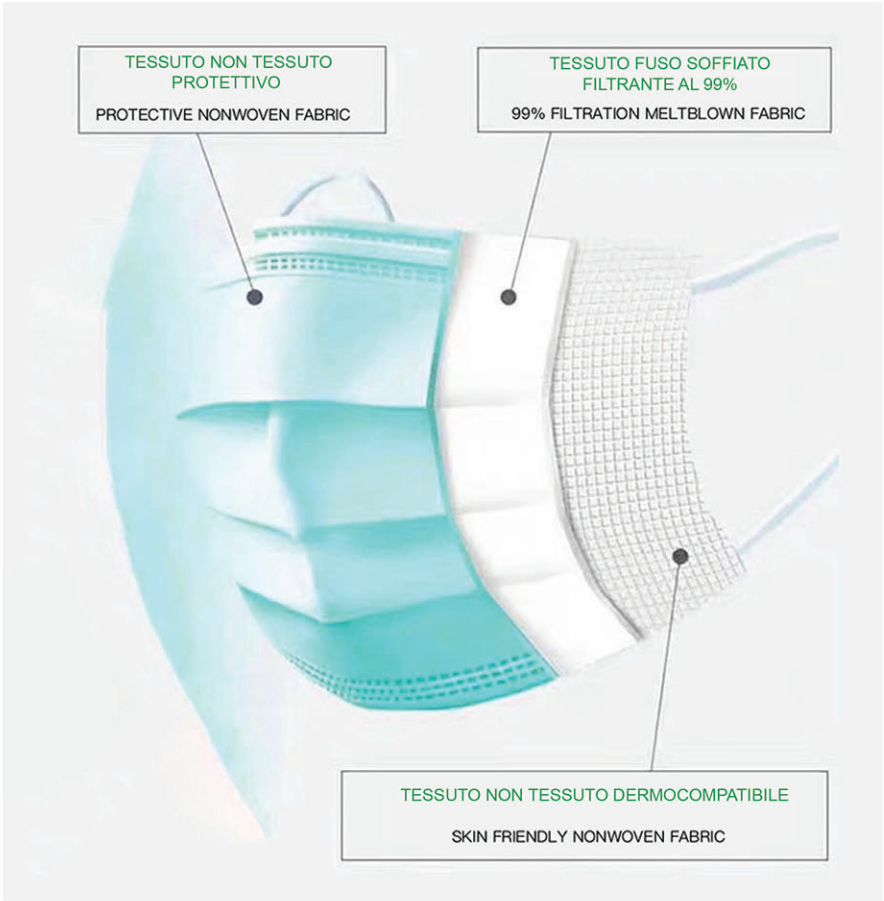
ALL'INTERNO DELLA NOSTRA FABBRICA ABBIAMO INSTALLATO UNA CAMERA BIANCA ISO CLASSE 5:100000 PARTICELLE 0,1 µM, UN AMBIENTE LA CUI CARATTERISTICA PRINCIPALE È LA PRESENZA DI UN BASSISSIMO CONTENUTO DI MICRO PARTICELLE DI POLVERE IN SOSPENSIONE, CHE CONSENTE LA PRODUZIONE DI GRANDI QUANTITÀ DI MASCHERINE IN MANIERA COMPLETAMENTE STERILE.

INSIDE OUR FACTORY WE HAVE INSTALLED A CLEAN ROOM ISO CLASS 5:100000 PARTICLES 0.1 µM, AN ENVIRONMENT CHARACTERISED BY A VERY LOW CONTENT OF SUSPENDED MICRO DUST PARTICLES, WHICH ALLOWS THE PRODUCTION OF LARGE QUANTITIES OF MASKS IN A COMPLETELY STERILE WAY.

MASCHERINA CHIRURGICA 3PLY TIPO IIR

LE MASCHERINE MEDICHE CHIRURGICHE IIR SONO IPOALLERGENICHE, HANNO UN'OTTIMA VESTIBILITÀ E PRESENTANO UNA BUONA RESISTENZA ALLA PENETRAZIONE BATTERICA, GRAZIE AL SUO POTERE FILTRANTE BFE ≥ 99%.
MASCHERINE CONFORMI ALLO STANDARD EUROPEO EN 14683:2019.

IIR MEDICAL SURGICAL MASKS ARE HYPOALLERGENIC, PROVIDE AN EXCELLENT FIT AND HAVE GOOD RESISTANCE TO BACTERIAL PENETRATION DUE TO ITS BFE ≥ 99% FILTERING POWER.
OUR MASKS COMPLY WITH THE EUROPEAN STANDARD EN 14683:2019.



MASCHERINA CHIRURGICA 3PLY TIPO IIR

TESSUTO NON TESSUTO PROTETTIVO

PROTECTIVE NONWOVEN FABRIC

TESSUTO FUSO SOFFIATO FILTRANTE AL 99%

99% FILTRATION MELTBLOWN FABRIC

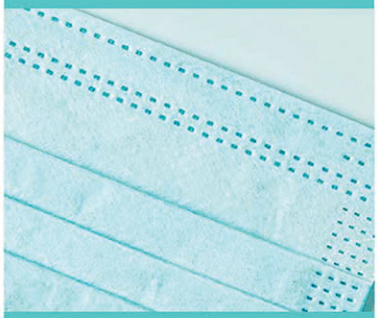
TESSUTO NON TESSUTO DERMOCOMPATIBILE

SKIN FRIENDLY NONWOVEN FABRIC

THREE LAYER FILTRATION DESIGN

FILTRAZIONE PROTETTIVA A TRE STRATI

ULTRASONIC WELDING DOTS



PUNTI DI SALDATURA AD ULTRASUONI

METAL CORE PLASTIC NOSEBRIDGE

NASELLO IN PLASTICA CON ANIMA IN METALLO

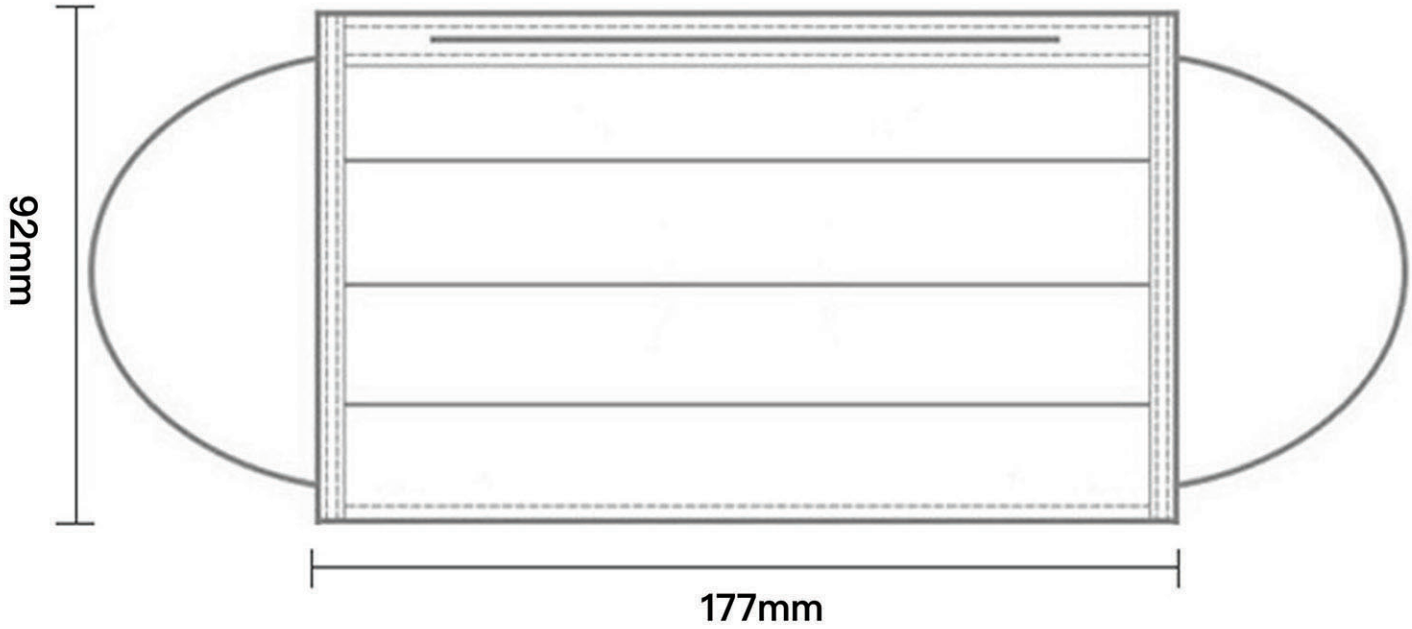
ELASTIC EARLOOP

LACCI ELASTICI PER ORECCHIE

DESCRIZIONE PRODOTTO

La mascherina Chirurgica 3-ply tipe IIR proteggere noi e gli altri essendo un dispositivo medico a 3 veli in TNT (tessuto non tessuto) melt-brown ad altra nitrazione, con strato esterno antispruzzo e strato interno dermocompatibile. Le mascherine vengono prodotte in ambiente sterile, in una camera bianca, per una maggiore sterilizzazione.

Questo dispositivo medico può rappresentare anche un opportunità per promuovere un brand o un prodotto. Un gadget che ha un altissima visibilità poiché le scritte o i loghi presenti sulle mascherine vengono notati da chiunque entri in contatto con le persone che la indossano.



DIMENSIONE: 92mm X 177mm

VALIDITÀ: 2 ANNI DALLA DATA DI PRODUZIONE

MATERIALI
TESSUTO NON TESSUTO PROTETTIVO
FILTRAGGIO CON TESSUTO MEL TBLOWN FINO AL 99%
TESSUTO NON TESSUTO DERMOCOMPATIBILE

STANDARD: IIR

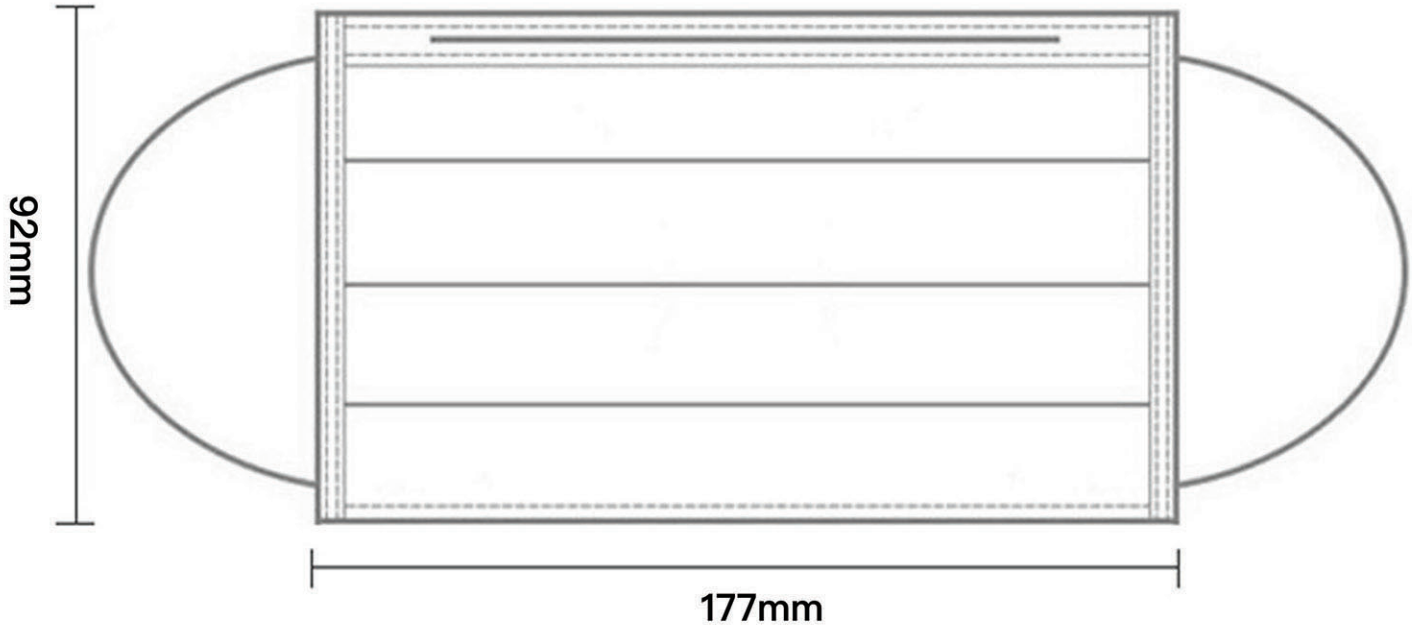
FILTRAGGIO: FINO AL 99% DEI MICRORGANISMI

PRODUCT DESCRIPTION

The IIR medical surgical masks is designed to protect the wearer and other people.

Our 3ply mask is made of three layers including an outer hydrophobic non-woven layer, a middle melt-blown layer, and an inner soft absorbent non-woven layer. The masks are produced in a sterile environment, a sterile clean room, for greater sterilisation.

Our 3-ply customised masks represent a great opportunity for you to promote your business. With our masks you won't go unnoticed anymore!



PRODUCT SIZE: 92mm X 177mm

EXPIRATION DATE: WITHIN 2 YEARS FROM THE PRODUCTION DATE

MATERIALS

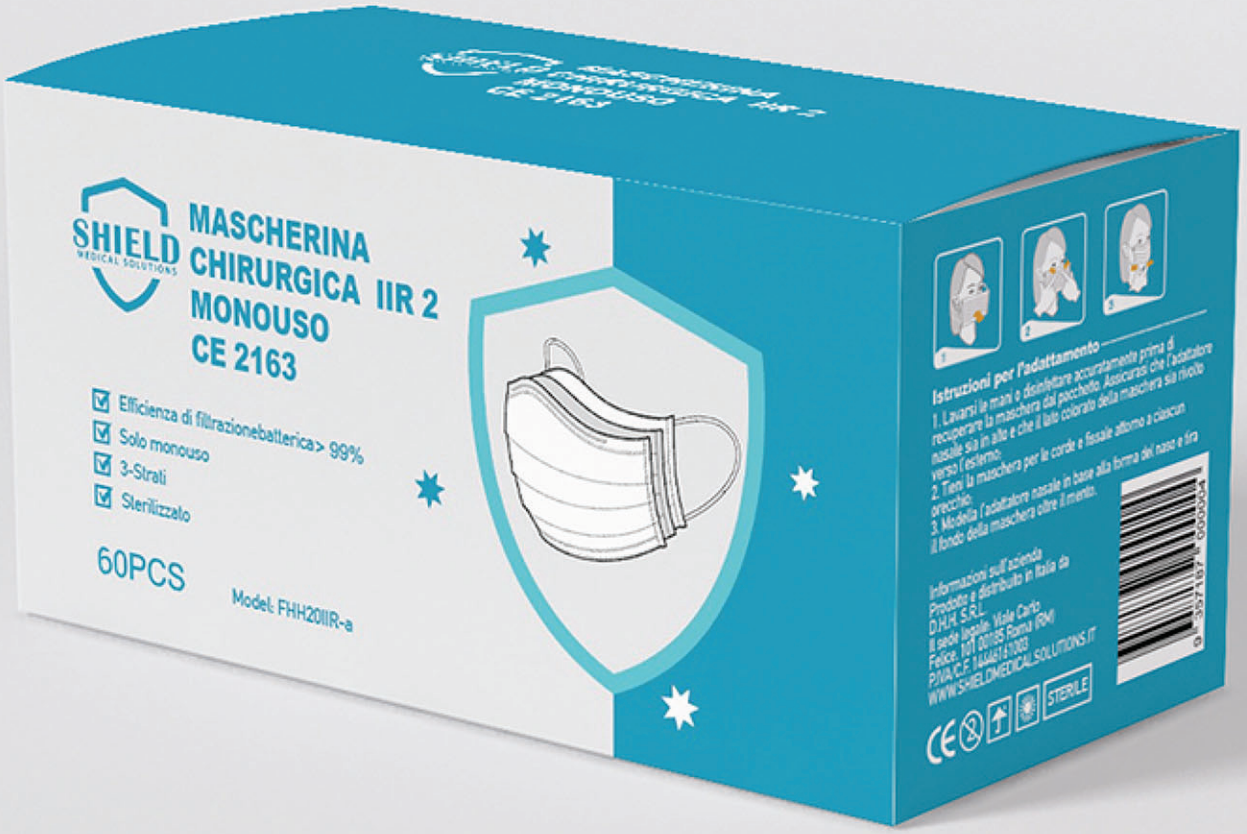
PROTECTIVE. NON-WOVEN FABRIC
99% FILTRATION THANKS TO A MELT-BLOWN FABRIC
DERMOCOMPATIBLE NON-WOVEN FABRIC

STANDARD: TYPE IIR

FILTRATION EFFICIENCY: CATCH 99% OF MICROORGANISMS

CONFEZIONE

PACKAGING



PRODUCT CERTIFICATIONS

EU DECLARATION OF CONFORMITY

MANUFACTURER
D.H.H. SRL
Via Campobello 30, 00071 Pomezia (RM), ITALY

PRODUCT DESCRIPTION
Layered and molded medical device classified in the Class I - Medical Device to be used as protection against inhalation of viruses, bacteria, other microorganisms, allergens from the environment

Model: DHH20
Type IIR

The Producer / the Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Producer's / the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- Government Regulation no. 93/42/EEC Medical devices establishing technical requirements for medical devices, in effective wording
- Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
- Other relevant harmonized legislation
- Other relevant local, national and community standards
- For the assessment of conformity, the following documents were also applied to:
- Tests for irritation and delayed-type hypersensitivity
- Results of laboratory tests Çevre Industrial Testing Laboratory Bacterial filtration efficiency
- Results of laboratory tests Çevre Industrial Testing Laboratory Microbial Cleanliness
- Results of laboratory tests Çevre Industrial Testing Laboratory Differential Pressure
- Results of laboratory tests Çevre Industrial Testing Laboratory Splash Resistance Pressure

MARKING, LABELLING
Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied:
type of mask (as indicated in Table 1). EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered

MEASURES TO ENSURE CONFORMITY
The Producer / the Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

General Manager
19/10/2020

D.H.H. SRL
Via Campobello 30
00071 Pomezia
P.IVA14446161003

CE

Certificato N. IT21/0018

SGS

Il sistema di gestione per la qualità di

D.H.H. S.r.l.

Sede Legale:
Viale C. Felice, 101 - 00185 ROMA - Italia
Sede Operativa:
Via Campobello, 30 - 00071 Pomezia (RM) - Italia

è stato verificato ed è risultato conforme ai requisiti di

ISO 9001 / UNI EN ISO 9001:2015

Scopo della certificazione:

Produzione di mascherine protettive.

Settore EA: 04

Questo certificato è valido dal 12/01/2021 fino al 12/01/2024.
La validità è subordinata all'esito soddisfacente dell'attività di sorveglianza periodica.
Ricertificazione da eseguirsi entro il 04/01/2024.
Rev. 1. Certificata dal 12/01/2021.

Data inizio audit: 04/01/2021.

SYSTEM CERTIFICATION ISO 9001 SGS

ACCREDIA

Autorizzato da
Paola Santarelli

SGS ITALIA S.p.A.
Via Caldera, 21 - 20153 MILANO - Italy
t. +39 02 73 93 1 f. +39 02 70 10 94 69 www.sgs.com

Pagina 1 di 1

PRODUCT CERTIFICATIONS

UNIVERSALCERT.COM

UNIVERSAL CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-284

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 Commission directive 2007/47/EC amending Medical Devices Directive dated 05 September 2007.

the products manufactured by

D.H.H. SRL

at the following address

Via Campobello 30, 00071 Pomezia (RM), ITALY

EN 14683:2019+AC:2019 Medical Face Masks

Model : DHH20
Type IIR
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 Çevre Industrial Testing Laboratory Bacterial Filtration Efficiency, Microbial Cleanliness, Differential Pressure and Splash Resistance Pressure tests.

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 19/10/2020 and valid until 18/10/2021 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.

ISTANBUL – 19/10/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

This certificate will be in the absence of any changes in standard and legal terms, and with the surveillance audits to be concuted annually following the surveillance audits, updating the publicationdate without changing the certificate number.

UNIVERSAL CERTIFICATION

TECHNICAL EVALUATION REPORT

REPORT DATE / NO: 19.10.2020 / 10-2020-T0460

Manufacturer: D.H.H. SRL
Address: Via Campobello 30, 00071 Pomezia (RM), ITALY

The medikal masks manufactured by the above manufacturer, are evaluated based on the Annex ZA of harmonised standard EN 14683/AC:2019 and the essential health and Safety requirements of 93/42/EEC, Medical Device Directive for Class I products on avoluntary base upon the manufacturer request.

Product Description: Medical Face Mask
Model: DHH20

As a third party evaluation, the technical file provided by the manufacturer is evaluated and the samples provided by the manufacturer are tested according to Annex ZA of the EN 14683/AC:2019 standard.
See Annex I: Test report provided by Çevre Endüstriyel Analiz Laboratuarı 16.10.2020 2022987E-R1 date and with report number.

This report or the issued certificate, in case the report is positive, does not take over orchange the sole reponsibility of the manufacturer covered under 93/42/EEC Medical Device Directive. The manufacturer shall fulfil all responsibilities for Class I products under 93/42/EEC Medical Device Directive.

UNIVERSAL CERTIFICATION

The results of the evaluation are as follows;

A- Review of the technical file

The manufacturer owns a technical file based on the requirements of 93/42/EEC Medical Device Directive in which the essential health and Safety requirements for Class I products are handled and have documented procedures to fulfil these requirements. The positive result of this report or the possible certificate to be issued based on positive result of this report shall not be used as the share of the responsibility of manufacturer on the fulfilment of any responsibility to be fulfilled before putting the product on the EU market.

B- Product Test Results

The tests referenced in Annex ZA are conducted on the samples provided by the manufacturer and the results are evaluated;

1. **Biocompatibility**

In the evaluation of the technical file, it was observed that the manufacturer ha established a mechanism for the evaluation of raw materials or semi-finished goods o their biocompatibility. The manufacturer claims that the request and evaluation of proof for biocompatiblity of the goods is an essential part of the procurement policy an declares that the produced masks are complies with the biocompatibility requirements an have authorised responsible staff members for ensuring the success of this policy. It i considered that the manufacturer have an effective policy for the biocompatibility of th product.

2. **Bacteria Filtration Efficiency**

At least 5 samples are subjected to a bacteria aerosol with a flow rate of 28.3 L/min for minutes with a test setup defined in the Annex B of EN 14683/AC:2019 standard. Wit the results of the incubation of samples taken in different particule sizes are shown in th annexed test report.

The minimum bacteria filtration efficiency performance required by each performance classes are shown below;

Test	Type I*	Type II	Type IIR
Bacterial Filtration Efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98

* Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

According to the evaluation of the results of 5 samples tested, the minimum bacteri filtration efficiency is given as **99,6%**. According to this result, the bacteria filtratio efficiency performance of the masks is classifified as **Type IIR.**

It was observed that the avarage positive control values and negative control value is als reported as a confidence parameter of the test result are meaningful.

3. **Microbial Cleanliness (Bioburden)**

It is expected to have the number of colony forming units per gram to be lower than 30 fo all performance class of masks according to the test result based on ISO 11737-1 standard

In the evaluation of the test result, the maximum count of the colony forming unit i reported as 3 For this test result the samples complies the requirement for all performanc classes (Type I, Type II and Type IIR).

UNIVERSAL CERTIFICATION

4. **Differentail Pressure**

The test is conducted to measure the breathing resistance as the differantial pressure and the expected result for Type I and Type II classes is not to be higher than 40 Pa/cm² and for Type IIR class not to be higher than 60 Pa/cm².

According to the test results, the highest differantial pressure measured is **34,6** Pa/cm² and the samples complies the requirement for all performance classes (Type I, Type II and Type IIR).

5. **Splash Resistance Pressure**

In the test, done according to ISO 22609:2004 the product's splash resistance is expected to be equal or higher than 16kpa for the Type 2R class.

All 15 samples tested were able to provide Type IIR performances as 16kPa resistance.

C- Summary and Conclusion

Evaluation	Requirement	Result	Classification
Bacterial Filtration Efficiency (BFE), (%)	≥ 95 % – Type I ≥ 98 % – Type II ≥ 98 % – Type IIR	99,6 %	Type I Type II Type IIR
Differential pressure (Pa/cm2)	< 40 – Type I < 40 – Type II < 60 – Type IIR	34,6	Type I Type II Type IIR
Splash resistance pressure (kPa)	Not Required – Type I Not Required – Type II ≥ 16 – Type IIR	> 16	Type IIR
Microbial cleanliness (cfu/g)	≤ 30 – Type I ≤ 30 – Type II ≤ 30 – Type IIR	3	Type I Type II Type IIR
Overall Performance Classification			**Type IIR**

– End of Report –

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ.
Necip Fazıl Bulvarı, Koyap Sitesi, E2 Blok, No:44/84
Yukarı Dudullu-Ümraniye/İSTANBUL
Telefon: 0216 455 80 80 Faks: 0216 455 80 08
Sanayi V.D. 893 026 6722

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

MASCHERINE FACCIALI FILTRANTI FFP2 NR

FFP2 NR FILTERING FACE MASKS

LE MASCHERINE FFP2 NR SONO IPOALLERGENICHE E IMPERMEABILI, HANNO UN'OTTIMA VESTIBILITÀ, GARANTISCONO UN AGEVOLE FLUSSO D'ARIA IN ENTRAMBE LE DIREZIONI, POICHÉ TRASPIRANTI, E PRESENTANO UNA BUONA RESISTENZA ALLA PENETRAZIONE BATTERICA, GRAZIE AL SUO POTERE FILTRANTE BFE ≥ 99 %. MASCHERINE CONFORMI ALLO STANDARD EUROPEO EN 149:2001

FFP2 NR FILTERING MASKS ARE HYPOALLERGENIC AND WATERPROOF, THEY PROVIDE AN EXCELLENT FIT, GUARANTEE AN EASY AIR FLOW IN BOTH DIRECTIONS AND HAVE A GOOD RESISTANCE TO BACTERIAL PENETRATION, THANKS TO ITS BFE ≥ 99 % FILTERING POWER.
OUR MASKS COMPLY WITH THE EUROPEAN STANDARD EN 149:2001

MASCHERINE FACCIALI FILTRANTI FFP2 NR

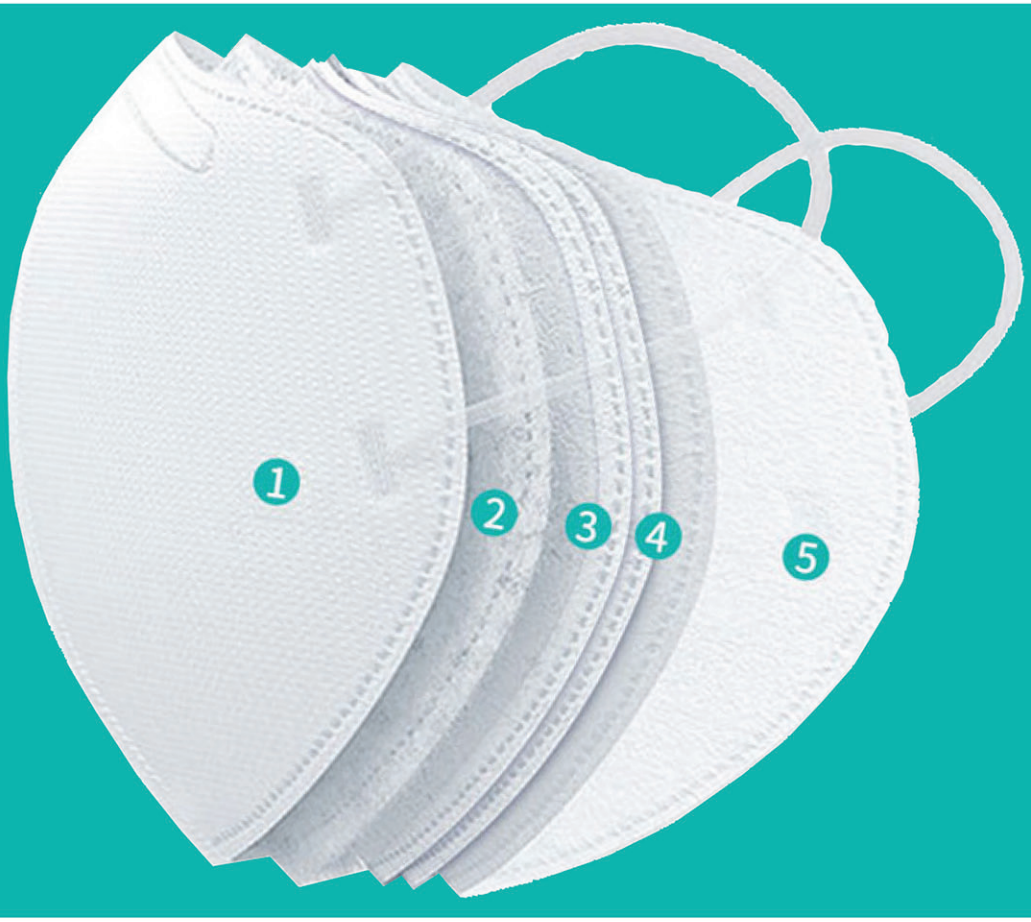
FFP2 NR FILTERING FACE MASKS

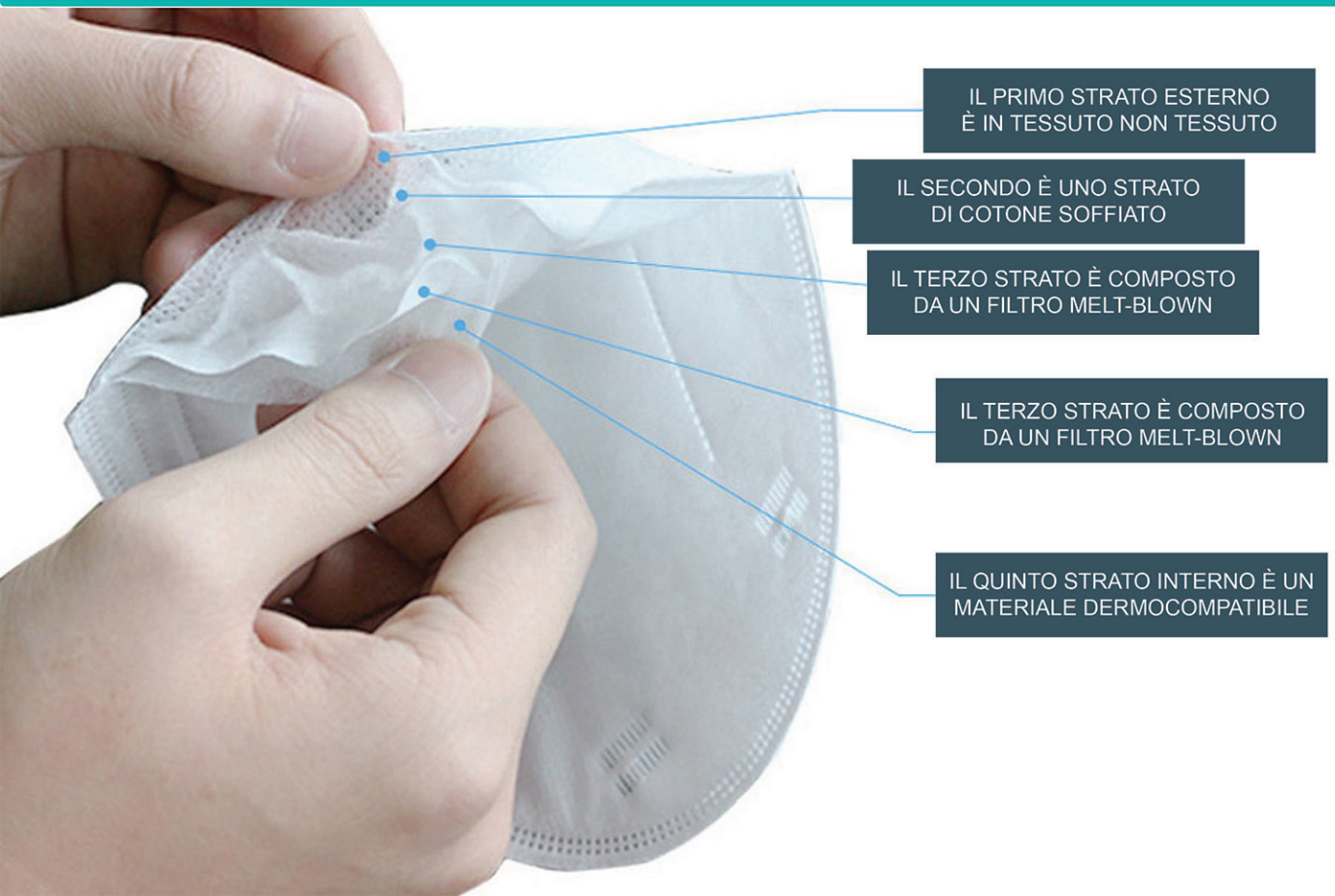
1. PROTECTIVE NONWOVEN 50 GSM

2. HOT AIR FABRIC 50 GSM

3. MELT-BLOWN 25 GSM

4. SKIN FRIENDLY NONWOVEN 25 GSM





IL PRIMO STRATO ESTERNO È IN TESSUTO NON TESSUTO

IL SECONDO È UNO STRATO DI COTONE SOFFIATO

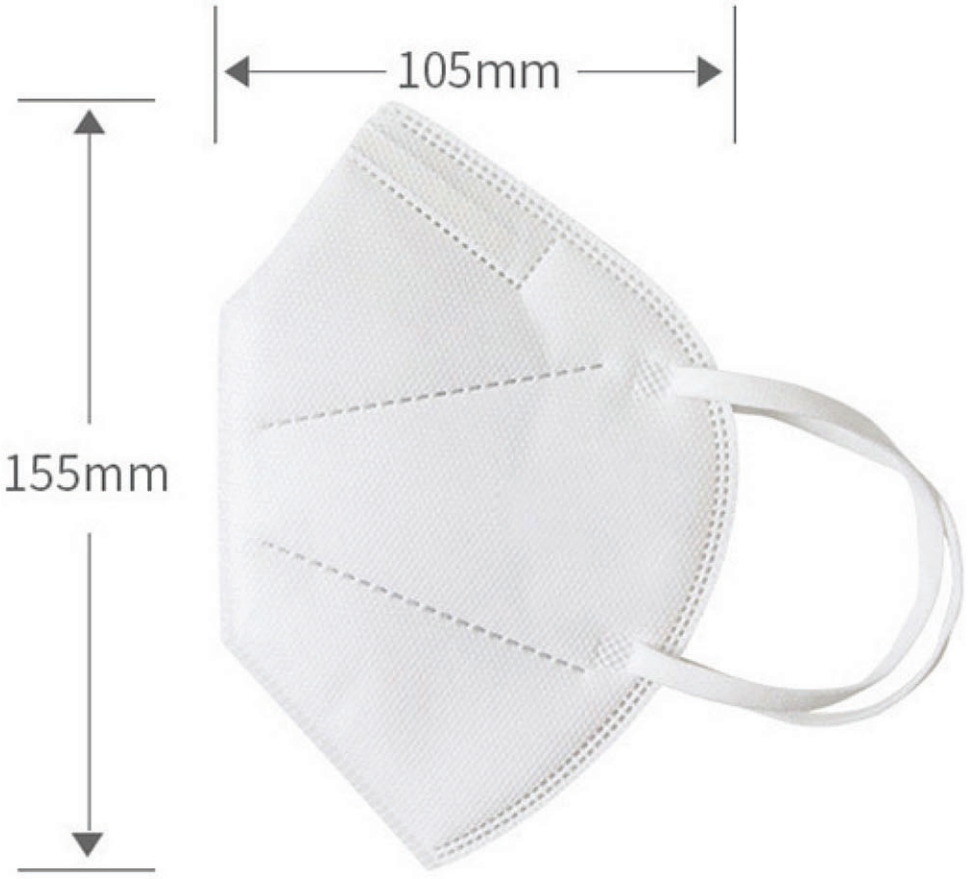
IL TERZO STRATO È COMPOSTO DA UN FILTRO MELT-BLOWN

IL TERZO STRATO È COMPOSTO DA UN FILTRO MELT-BLOWN

IL QUINTO STRATO INTERNO È UN MATERIALE DERMOCOMPATIBILE

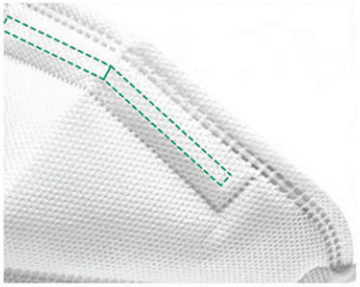
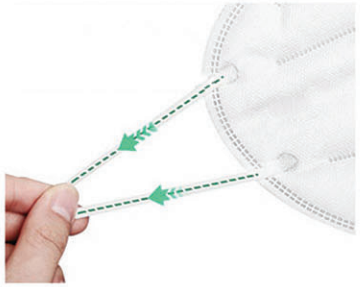
CARATTERISTICHE DEL PRODOTTO

PRODUCT PARAMETERS



Tutte le misure vengono rilevate a mano. Potrebbero esserci degli errori.
Si prega di fare riferimento ai parametri presenti nel prodotto.

All dimensions are measured by hand. There may be errors.
Please refer to the actual products.

ULTRASONIC WELDING DOTS	SKIN FRIENDLY NONWOVEN	METAL CORE PLASTIC NOSEBRIDGE	ELASTIC EARLOOP
			
PUNTI DI SALDATURA AD ULTRASUONI	TNT DERMOCOMPATIBILE	NASELLO IN PLASTICA CON ANIMA IN METALLO	LACCI ELASTICI PER ORECCHIE

CONFEZIONE

PACKAGING

PRODUCT CERTIFICATION

UNIVERSAL

UNIVERSAL
CERTIFICATION
NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1587

Respiratory protective devices, filtering half masks to protect against particles manufactured by

D.H.H. SRL
Via Campobello 30, 00071 Pomezia (RM) Sede ITALY

are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Model: DHH20M
Filtering half mask
Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **19/10/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - ISTANBUL - TURKEY T:+90 216 455 80 80

UNIVERSALCERT.COM

MASCHERINE PERSONALIZZATE

CUSTOMISED MASKS

OPPORTUNITÀ PER I BRAND SI ESSERE VISIBILI

A REAL OPPORTUNITY FOR COMPANIES TO BE VISIBLE

CON LA NOSTRA TECNOLOGIA PUOI POSIZIONARE LA STAMPA ESATTAMENTE AL CENTRO

THANKS TO OUR HIGH TECHNOLOGY, YOU CAN PLACE THE PRINT EXACTLY IN THE CENTRE

MASCHERINE PERSONALIZZATE

CUSTOMISED MASKS

- TESTATO E CERTIFICATO UNIVERSAL
- STANDARD MEDICO ELEVATO TIPO IIR
- 99.8% EFFICIENZA FILTRAGGIO
- 100% UTILIZZO SICURO, LA STAMPA NON RILASCIA RESIDUI O ODORI

- TESTED AND CERTIFIED BY UNIVERSAL
- HIGHEST MEDICAL STANDARDS: TYPE IIR
- 99.8 % OF FILTRATION EFFICIENCY
- 100% SAFE. NO PRINT RESIDUALS OR ODOURS MICRODROPLETS

MICRO GOCCE

MICRODROPLETS

FUMO

SMOG

ODORI

ODOURS

POLVERE

DUST

MASCHERINE CLUB SPORTIVI

SPORT CLUB FACE MASKS

STILE E SICUREZZA!

Le nostre mascherine non sono solo estremamente eleganti e personalizzabili, ma anche sicure al 100%. Tutte le nostre mascherine sono sterili e costituite da tre strati di tessuto non tessuto ad alta tecnologia di filtrazione.

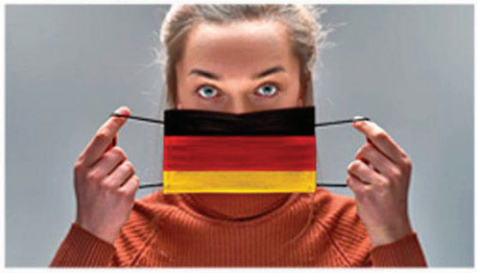
STYLE AND SAFETY!

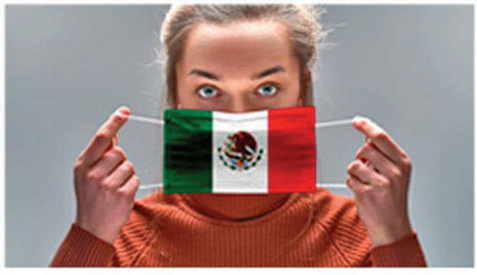
Not only our masks are extremely stylish and customisable, but they are also 100% safe! All our masks are sterile and made of three-layers of non-woven fabric with a high filtration technology.

BANDIERE NAZIONALI

NATIONAL FLAGS

Una vera innovazione nel settore turistico! Le nostre mascherine a 3 strati personalizzate saranno un perfetto souvenir da portare a casa!





A real innovation in the tourism sector! Our customised 3-ply masks will be the perfect souvenir to bring back home!

MASCHERINE PER BAMBINI

KIDS MASKS

SHIELD
MEDICAL SOLUTIONS

CONFEZIONAMENTO SINGOLO

INDIVIDUAL PACKAGING

PRODUCT CERTIFICATIONS

EU DECLARATION OF CONFORMITY

MANUFACTURER
D.H.H. SRL
Via Campobello 30, 00071 Pomezia (RM), ITALY

PRODUCT DESCRIPTION
Layered and molded medical device classified in the Class I - Medical Device to be used as protection against inhalation of viruses, bacteria, other microorganisms, allergens from the environment

Model: DHH20
Type IIR

The Producer / the Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Producer's / the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- Government Regulation no. 93/42/EEC Medical devices establishing technical requirements for medical devices, in effective wording
- Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
- Other relevant harmonized legislation
- Other relevant local, national and community standards
- For the assessment of conformity, the following documents were also applied to:
- Tests for irritation and delayed-type hypersensitivity
- Results of laboratory tests Çevre Industrial Testing Laboratory Bacterial filtration efficiency
- Results of laboratory tests Çevre Industrial Testing Laboratory Microbial Cleanliness
- Results of laboratory tests Çevre Industrial Testing Laboratory Differential Pressure
- Results of laboratory tests Çevre Industrial Testing Laboratory Splash Resistance Pressure

MARKING, LABELLING
Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied:
type of mask (as indicated in Table 1). EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered

MEASURES TO ENSURE CONFORMITY
The Producer / the Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

General Manager
19/10/2020

D.H.H. SRL
Via Campobello 30
00071 Pomezia
P.IVA14446161003

CE

Certificato N. IT21/0018

SGS

Il sistema di gestione per la qualità di

D.H.H. S.r.l.

Sede Legale:
Viale C. Felice, 101 - 00185 ROMA - Italia
Sede Operativa:
Via Campobello, 30 - 00071 Pomezia (RM) - Italia

è stato verificato ed è risultato conforme ai requisiti di

ISO 9001 / UNI EN ISO 9001:2015

Scopo della certificazione:

Produzione di mascherine protettive.

Settore EA: 04

Questo certificato è valido dal 12/01/2021 fino al 12/01/2024.
La validità è subordinata all'esito soddisfacente dell'attività di sorveglianza periodica.
Ricertificazione da eseguirsi entro il 04/01/2024.
Rev. 1. Certificata dal 12/01/2021.

Data inizio audit: 04/01/2021.

SYSTEM CERTIFICATION ISO 9001 SGS

ACCREDIA

Autorizzato da
Paola Santarelli

SGS ITALIA S.p.A.
Via Caldera, 21 - 20153 MILANO - Italy
t. +39 02 73 93 1 f. +39 02 70 10 94 69 www.sgs.com

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PRODUCT CERTIFICATIONS

UNIVERSALCERT.COM

UNIVERSAL CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate Nr: MDD-284

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 Commission directive 2007/47/EC amending Medical Devices Directive dated 05 September 2007.

the products manufactured by

D.H.H. SRL

at the following address

Via Campobello 30, 00071 Pomezia (RM), ITALY

EN 14683:2019+AC:2019 Medical Face Masks

Model : DHH20
Type IIR
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 Çevre Industrial Testing Laboratory Bacterial Filtration Efficiency, Microbial Cleanliness, Differential Pressure and Splash Resistance Pressure tests.

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 19/10/2020 and valid until 18/10/2021 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.

ISTANBUL – 19/10/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

This certificate will be in the absence of any changes in standard and legal terms, and with the surveillance audits to be concuted annually following the surveillance audits, updating the publicationdate without changing the certificate number.

UNIVERSAL CERTIFICATION

TECHNICAL EVALUATION REPORT

REPORT DATE / NO: 19.10.2020 / 10-2020-T0460

Manufacturer: D.H.H. SRL
Address: Via Campobello 30, 00071 Pomezia (RM), ITALY

The medikal masks manufactured by the above manufacturer, are evaluated based on the Annex ZA of harmonised standard EN 14683/AC:2019 and the essential health and Safety requirements of 93/42/EEC, Medical Device Directive for Class I products on avoluntary base upon the manufacturer request.

Product Description: Medical Face Mask
Model: DHH20

As a third party evaluation, the technical file provided by the manufacturer is evaluated and the samples provided by the manufacturer are tested according to Annex ZA of the EN 14683/AC:2019 standard.
See Annex I: Test report provided by Çevre Endüstriyel Analiz Laboratuarı 16.10.2020 2022987E-R1 date and with report number.

This report or the issued certificate, in case the report is positive, does not take over orchange the sole reponsibility of the manufacturer covered under 93/42/EEC Medical Device Directive. The manufacturer shall fulfil all responsibilities for Class I products under 93/42/EEC Medical Device Directive.

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The results of the evaluation are as follows;

A- Review of the technical file

The manufacturer owns a technical file based on the requirements of 93/42/EEC Medical Device Directive in which the essential health and Safety requirements for Class I products are handled and have documented procedures to fulfil these requirements. The positive result of this report or the possible certificate to be issued based on positive result of this report shall not be used as the share of the responsibility of manufacturer on the fulfilment of any responsibility to be fulfilled before putting the product on the EU market.

B- Product Test Results

The tests referenced in Annex ZA are conducted on the samples provided by the manufacturer and the results are evaluated;

1. **Biocompatibility**

In the evaluation of the technical file, it was observed that the manufacturer ha established a mechanism for the evaluation of raw materials or semi-finished goods o their biocompatibility. The manufacturer claims that the request and evaluation of proof for biocompatiblity of the goods is an essential part of the procurement policy an declares that the produced masks are complies with the biocompatibility requirements an have authorised responsible staff members for ensuring the success of this policy. It i considered that the manufacturer have an effective policy for the biocompatibility of th product.

2. **Bacteria Filtration Efficiency**

At least 5 samples are subjected to a bacteria aerosol with a flow rate of 28.3 L/min for minutes with a test setup defined in the Annex B of EN 14683/AC:2019 standard. Wit the results of the incubation of samples taken in different particule sizes are shown in th annexed test report.

The minimum bacteria filtration efficiency performance required by each performance classes are shown below;

Test	Type I*	Type II	Type IIR
Bacterial Filtration Efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98

* Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

According to the evaluation of the results of 5 samples tested, the minimum bacteri filtration efficiency is given as **99,6%**. According to this result, the bacteria filtratio efficiency performance of the masks is classifified as **Type IIR.**

It was observed that the avarage positive control values and negative control value is als reported as a confidence parameter of the test result are meaningful.

3. **Microbial Cleanliness (Bioburden)**

It is expected to have the number of colony forming units per gram to be lower than 30 fo all performance class of masks according to the test result based on ISO 11737-1 standard

In the evaluation of the test result, the maximum count of the colony forming unit i reported as 3 For this test result the samples complies the requirement for all performanc classes (Type I, Type II and Type IIR).

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4. **Differentail Pressure**

The test is conducted to measure the breathing resistance as the differantial pressure and the expected result for Type I and Type II classes is not to be higher than 40 Pa/cm² and for Type IIR class not to be higher than 60 Pa/cm².

According to the test results, the highest differantial pressure measured is **34,6** Pa/cm² and the samples complies the requirement for all performance classes (Type I, Type II and Type IIR).

5. **Splash Resistance Pressure**

In the test, done according to ISO 22609:2004 the product's splash resistance is expected to be equal or higher than 16kpa for the Type 2R class.

All 15 samples tested were able to provide Type IIR performances as 16kPa resistance.

C- Summary and Conclusion

Evaluation	Requirement	Result	Classification
Bacterial Filtration Efficiency (BFE), (%)	≥ 95 % – Type I ≥ 98 % – Type II ≥ 98 % – Type IIR	99,6 %	Type I Type II Type IIR
Differential pressure (Pa/cm2)	< 40 – Type I < 40 – Type II < 60 – Type IIR	34,6	Type I Type II Type IIR
Splash resistance pressure (kPa)	Not Required – Type I Not Required – Type II ≥ 16 – Type IIR	> 16	Type IIR
Microbial cleanliness (cfu/g)	≤ 30 – Type I ≤ 30 – Type II ≤ 30 – Type IIR	3	Type I Type II Type IIR
Overall Performance Classification			**Type IIR**

– End of Report –

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ.
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Yukarı Dudullu-Ümraniye/İSTANBUL
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