



CERTIFICATO CE

Certificato n. 1951/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

3A HEALTH CARE S.r.l.

25017 LONATO DEL GARDA (BS) - VIA MARZIALE CERUTTI 90F/G (ITA) - Italy

mantiene nello stabilimento di:

25017 LONATO DEL GARDA (BS) - VIA MARZIALE CERUTTI 90F/G (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Apparecchi per aerosolterapia

Accessori per apparecchi per aerosolterapia

Aspiratori

Aspiratori per ambulanza

Modd. come da documento "Elenco prodotti 3A HEALTH CARE S.r.l." Rev. 04 del 04/02/2019; valido solo se provvisto del timbro IMQ.

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

DM17-0016835-01; DM18-0024812-01; DM18-0029038; DM18-0034026-01; DM19-0036397-01; DM19-0038533-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2017-11-18
Data aggiornamento: 2019-07-16
Sostituisce: 2019-04-02
Data scadenza: 2024-05-26

IMQ



EC CERTIFICATE

Certificate No 1951/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

3A HEALTH CARE S.r.l.

25017 LONATO DEL GARDA (BS) - VIA MARZIALE CERUTTI 90F/G (ITA) - Italy

manages in the factory of:

25017 LONATO DEL GARDA (BS) - VIA MARZIALE CERUTTI 90F/G (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Aerosoltherapy equipment

Accessories for aerosoltherapy equipment

Suction equipments

Suction equipments for ambulance

Type ref. as to document "List of devices 3A HEALTH CARE S.r.l." Rev. 04 dated 04/02/2019; valid only if provided with IMQ stamp.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM17-0016835-01; DM18-0024812-01; DM18-0029038; DM18-0034026-01; DM19-0036397-01; DM19-0038533-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date: 2017-11-18
Updated: 2019-07-16
Substitution Date: 2019-04-02
Expiry Date: 2024-05-26

IMQ



Elenco prodotti
List of devices
3A HEALTH CARE S.r.l.

Date: **04/02/2019**

Rev. **04**

Apparecchi per aerosolterapia
Aerosoltherapy equipment

Modello
Model : **HAPPYNEB II ; HAPPYNEB III ; AIRJOLIE 2 DELUXE ; HOSPYNEB professional ;
COMP-A NEB ; ATOMIZER ; RESPIRO ; ISINEB ; NEBBY ; NEBBY PLUS ; SPEEDY ; PICONEB ;
FUN-NEB ; MIDINEB ; MIKRONEB ; MYNEB ; TURBONEB ;**

Trade mark: 3A HEALTH CARE S.r.l.

Modello
Model : **AEROSAN + Trade mark: Messer Medical ;
JC-117 ; JC-118 ; JC-118G ; JC-1301; JC-117P Trade mark: Joycare;
m213A Trade mark: Medicura ;
Salus 54901 Trade mark: Olimpico ;
DOCTORNEB Trade mark: Imetec ;
AIROFAMILY MAX Trade mark: Airssential Home ;
Beper 40.110 Trade mark: Beper ;
SANITY Inhalator PRO Trade mark: Sanity ;
TARTU' ; Arya ; Kosmo Trade mark: Prontex ;
LTK150 - NYXY ; LTK160 - NYXY FAMILY ; LTK170 - NYXY PRO ;
LT139- Hospyneb professional Trade mark: Moretti ;
Inhalator Amineb 2 Trade mark: PMT ;
NIVEC III Trade mark: MGE ;
ECONEB Trade mark: Trister ;
Air 100 Trade mark: Colpharma ;**



2019-07-16



Elenco prodotti
List of devices
3A HEALTH CARE S.r.l.

Date: **04/02/2019**

Rev. **04**

Accessori per apparecchi per Aerosolterapia
Accessories for aerosoltherapy equipment

Modello (codice)
Model (code):
Forcella nasale (NEB103); Tubo di collegamento (NEB104); Mascherina adulto (NEB105); Mascherina pediatrica (NEB106); Boccaglio (NEB202); Ampolla FASTERJET (NEB101) ; Kit accessori FASTERJET (NEB100) ; Boccaglio con valvola (NEB102); Kit accessori FASTERJET (NEB120) ; Kit accessori FASTERJET (NEB130); Kit accessori FASTERJET (NEB140); Kit accessori FASTERJET per TURBONEB (NEB141) ; Kit accessori FASTERJET (NEB150); Kit accessori FASTERJET (NEB160); Ampolla NEBJET con connettore (NEB201); Kit accessori NEBJET (NEB200); Kit accessori NEBJET (NEB220) ; Kit accessori NEBJET (NEB230); Kit accessori NEBJET (NEB240); Kit accessori NEBJET (NEB250) ; Kit accessori NEBJET (NEB260); Ampolla TECHNOJET (NEB1000); Kit accessori TECHNOJET (NEB1002); Ampolla QUICKJET con connettore (NEB3001); Kit accessori QUICKJET (NEB3000); NASALJET (NEB5000); NASALJET basic ;

Trade mark: 3A HEALTH CARE S.r.l.

Modello (codice)
Model (code):
Kit accessori ADAPTAIR N300K2 (NEB1001); Kit accessori NEBJET (NEB270); Doccia micronizzata Corman N100D (NEB5001)
Trade mark: Corman ;
kit accessori NEBJET c/mascherina pediatrica (NEB214); kit accessori NEBJET c/mascherina adulto (NEB215); Ampolla NEBJET (NEB217);
Trade mark: PMT ;
NASALJET - LTK185 (NEB5009); Ampolla FASTERJET - LTR140 (NEB129); Ampolla NEBJET - LTR141 (NEB225) Trade mark: Moretti ;
Rapid Mask - kit completo per aerosolterapia (NEB248); Rapid Ampolla nebulizzatrice con raccordo e curva (NEB249); RHINO CARE Trade mark: Prontex ;
Kit accessori NEBJET (NEB226) Trade mark: Messer Medical ;
Kit ampolla NEBJET +nasale+boccaglio+filtri (NEB219); Kit accessori NEBJET+filtri (NEB241)
Trade mark: Rosner ;
SANITY Nosalek JET (NEB5007); Kit accessori Sanity Inhalator Pro (NEB1028); Ampolla Sanity Inhalator Pro (NEB1029)
Trade mark: Sanity
Ampolla NEBJET 5317 - BN3050 (NEB239); Raccordo snodabile 5317 - BN3070 (NEB242); Kit nasale/boccaglio 5317 - BN3040 (NEB243); Maschera adulto 5317-BN3030 (NEB244); Tubo aria 1 mt 5317-BN3020 (NEB245); Mascherina regol. GWM 5317-BN3010 (NEB246)
Trade mark: Imetec ;
Doccia nasale LAICA ANE052 (NEB5010)
Trade mark: Laica ;



2019-07-16



Elenco prodotti
List of devices
3A HEALTH CARE S.r.l.

Date: **04/02/2019**

Rev. **04**

Aspiratori

Suction Equipments

Modello
Model : **ASPEED PROFESSIONAL - 1 POMPA; ASPEED PROFESSIONAL - 2 POMPE; ASPEED 3.0; ASPEED 2 - 1 POMPA; ASPEED 2 - 2 POMPE; MINIASPEED BATTERY PLUS; MINIASPEED BATTERY PRO; MINIASPEED BATTERY EVO; MAXIASPEED 6.2; MAXIASPEED 6.2P; MAXIASPEED 6.4; MAXIASPEED 6.4P; MAXIASPEED 9.2; MAXIASPEED 9.2P; MAXIASPEED 9.4; MAXIASPEED 9.4P**

Trade mark: 3A HEALTH CARE S.r.l.

Modello
Model : **SAM HOSPY 2 POMPE; SAM 420 LX Trade mark: MGE ; Promedic SP-00 ; Promedic SP-01 Trade mark: Trimpeks; VORTECO AS-100 EMERGENCY Trade mark: Alsa ; IREDEEM MINIASPEED BATTERY EVO Trade mark: Iredeem ; ASPIMED 1.8 - LTA410; ASPIMED 1.8 - LTA415; ASPIMED 1.9 - LTA420; ASPIMED 4.1; ASPIMED 4.2 Trade mark: Moretti ;**

Aspiratori per ambulanza

Suction equipments for ambulance

Modello
Model : **MINIASPEED BATTERY EVO PLUS Trade mark: 3A HEALTH CARE S.r.l. IREDEEM MINIASPEED BATTERY EVO PLUS Trade mark: Iredeem ;**



2019-07-16



Elenco prodotti
List of devices
3A HEALTH CARE S.r.l.

Date: **04/02/2019**

Rev. **04**

Categoria prodotto: Product Category:		Apparecchi per aerosolterapia Aerosoltherapy equipment
Descrizione del prodotto: Nebulizzatore a compressore <i>Product description: Compressor Nebulizer</i>		
Modello (codice) Model (code):	A3 Complete (NE-C300-ITA) ; A3 Complete (NE-C300-E) ; A3 Complete (NE-C300-D) ; A3 Complete (NE-C300-KSA) ; A3 Complete (NE-C300-UK) ; NE-C300 Complete (NE-C300-RU) ; CompAIR ECO (NE-C302-E) ; DuoBaby (NE-C301-KSA) ; DuoBaby (NE-C301-RU) ; C102 Total (NE-C102-E) ; C102 Total (NE-C102-ITA) ; Compact Plus (NE-C102-D) ; C102 Total (NE-C102-UK) ; C102 Total (NE-C102-KSA) ; C25 (NE-C102-RU) ;	
Descrizione del prodotto: Nebulizzatore a compressore con aspiratore nasale <i>Product description: Compressor Nebulizer with Nasal Aspirator</i>		
Modello (codice) Model (code):	DuoBaby (NE-C301-ITA); DuoBaby (NE-C301-E); DuoBaby (NE-C301-D); DuoBaby (NE-C301-UK); DuoBaby (NE-C301-AP);	
Trade mark: Omron		

Categoria prodotto: Product Category:		Accessori per apparecchi per aerosolterapia Accessories for aerosoltherapy equipment
Descrizione del prodotto: Kit ampolla <i>Product description: Kit Nebulizer Chamber</i>		
Modello (codice) Model (code):	A3 Complete Accessory Kit (NEB6001) ; NE-C300 Nebulizer kit (NEB6002) ; NE-C300 Complete Accessory Kit (NEB6003) ; Air Tube (NEB6004) ; Mouthpiece (NEB6005) ; Nosepiece (NEB6006) ; Adult Mask (NEB6007) ; Child Mask (NEB6008) ; NE-C301 Nebulizer kit (NEB6010) ; NE-C301 Nebulizer kit (NEB6011) ; Nebulizer kit (NEB6013) ; Adapter (NEB6015) ; NE-C301 Air Tube (NEB6016) ; CompAIR ECO Accessory set (NEB224) ; DuoBaby Nebulizer Accessory set (NEB2012) ; Accessory set-1 for C101, C102 (NEB6020) ; Accessory set-2 for C101, C102 (NEB6021) ; Accessory set-3 for C101, C102 (NEB6022) ;	
Descrizione del prodotto: Doccia Nasale <i>Product description: Nasal Shower</i>		
Modello (codice) Model (code):	A3 Complete Nasal Shower (NEB5006) ; Nasal shower (NEB6014) ;	
Descrizione del prodotto: Aspiratore Nasale <i>Product description: Nasal Aspirator</i>		
Modello (codice) Model (code):	DuoBaby Aspirator Accessory set (NEB7000); NE-C301 Aspirator (NEB6012) ;	
Trade mark: Omron		





Elenco prodotti
List of devices
3A HEALTH CARE S.r.l.

Date: **04/02/2019**

Rev. **04**

Apparecchi per aerosolterapia
Aerosoltherapy equipment

Modello
Model : **10120 - NEB 100 COMPACT BASIC, 10121 - NEB 100 COMPACT, 10122 - NEB 50 FAST, 10123 - PROFESSIONAL NEB 10, NEB 100A, NEB 100B, NEB 100, NEB 50A, NEB 50B, NEB 50, NEB 10A, NEB 10B, NEB 10, NEB 1000**

Trade mark: Microlife

Modello
Model : **COMPACT**
Trade mark: Aponorm

Modello
Model : **N280**
Trade mark: Accurete

Accessori per apparecchi per Aerosolterapia
Accessories for aerosoltherapy equipment

Modello
(Codice)
Model
(Code): **Adult mask NEB10/NEB100 2G+3G s993100-0 (NEB108); Child Mask NEB10/NEB100 s993101-0 (NEB109); Mouthpiece w/valve NEB10 s993003-0 (NEB111); IMPACTOR (2 pcs.) NEB100 (NEB122); NEBKIT Nebjet (NEB206); NEB nebulizer s993052-0 (NEB207); Mouthpiece NEB100 s993053-0 (NEB208); Tube NEB10/NEB100 s993102-0 (NEB209); Nosepiece NEB10/NEB100 (NEB210); Accessories kit NEBJET S993051 (NEB221); Mouthpiece NEB100 RU (NEB222); NEBKIT Nebjet RU (NEB223); NEBKIT Technojet s953002-0 (NEB1003); Technojet NEB10 3G s953001-0 (NEB1005); FASTERJET KIT 3G s953005-0 (NEB1010); NEB PRO for NEB50 (NEB 1011); NEBPRO +mouthpiece s953004-0 (NEB1013); NEBJET neb+mouthpiece s953006-0 (NEB1014); NEB PRO nebulizer mouthpiece with valve Belarus (NEB1015); NEB PRO PLUS nebulizer mouthpiece with valve Belarus (NEB1016); NEB nebulizer small set NEB100B (including mouthpiece) Belarus (NEB1017); TECHNOJET nebulizer S993002-0 (NEB 1023); Accessories kit TECHNOJET S993001 (NEB 1024); NEBJET neb+mouthpiece RU (NEB1025); Technojet NEB10 RU (NEB1026); NEBKIT Technojet RU (NEB1027); FASTERJET KIT 3G RU s953005-0 (NEB1031); NEBPRO +mouthpiece RU s953004-0 (NEB1032); Air Tube s993102-0 RU (NEB1033); Adult Mask s993100-0 RU (NEB1034); Mouthpiece w/valve s993003-0 RU (NEB1035); IMPACTOR (2 pcs.) NEB10 (NEB110); NEB 2in1 (NEB2009); Nasal Shower (NEB5004); kit 10124 - Doccia+ampolla+boccaglio (NEB2006); Kit accessori FASTERJET 10102 (NEB112); Ampolla FASTERJET 10103 (NEB113); Maschera adulto 10106 (NEB114); Maschera pediatrica 10107 (NEB115); Tubo di collegamento 10108 (NEB116); Boccaglio 10110 (NEB118); Boccaglio con valvola 10112 (NEB119); Nasale 10111 (NEB121); Kit accessori NEBJET 10104 (NEB211); Ampolla NEBJET 10105 (NEB212);**

Trade mark: Microlife

NEBKIT Nebjet 047410 (NEB227); Nebjet 047412 (NEB228); Mouthpiece 047411 (NEB229); Nosepiece 047408 (NEB231); Child Mask 047405 (NEB232); Adult Mask 047404 (NEB233); Tube w/bag 047406 (NEB234); Mouthpiece with valve 047394 (NEB236); Swivel connector 047396 (NEB237)

Trade mark: Aponorm

