Easypuff

Infant Resuscitation Device

User Manual

WARNING

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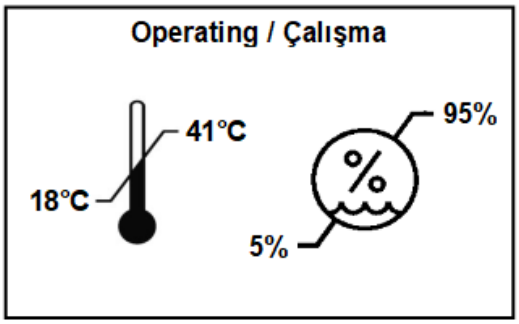
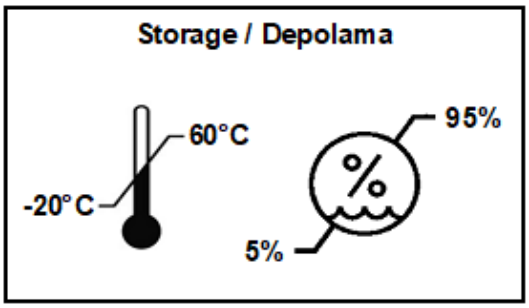
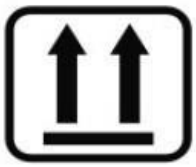
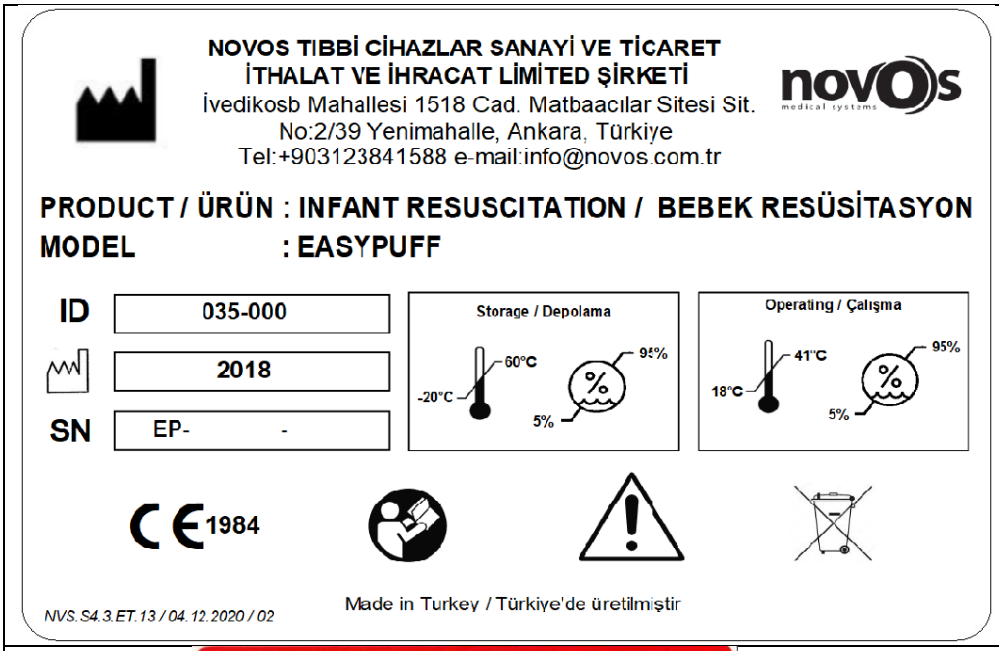
Symbols

	This symbol is used to warn the users of the device against possible risk or injury. Warnings are instructions that, if not followed, could result in fatal or serious injury to a user, engineer, patient, or other person, or could result in improper treatment.
ATTENTION	These are the guidances that may damage the system as described in this manual, if the attention notes are not followed.
NOTE:	NOTE is used where additional information on the subject is given.
ID	Product ID.
	Manufacturer.
	Date of Manufacture.
	Electrical and electronic equipment waste should not be disposed of in general municipal waste, but should be collected separately.
	CE mark Authorized body
	See User Manual
	Not sterile.

	Operation temperature and humidity range
	Storage temperature and humidity range
	Upright Direction of the Package
	Easily Fragile, Handle With Care
	Protect from moisture and rain

Labels on the Device



Device ID Label

Technical Service Warning

Outer Box Label

1. Safety Information

1.1. User Obligations for Patient Safety

ATTENTION	**Strictly follow this guide. Any use of the product requires thorough understanding and strict observation of all sections of these instructions. This equipment should only be used for the purpose specified in article "Intended Use". Follow all WARNING and ATTENTION notes stated in this manual and on the label on the device.**

The design of this equipment takes into account the relevant literature and labeling on the equipment, the purchase and use of this equipment is restricted to trained professionals and the specific features of the device are known to the trained operator. Therefore, instructions, warnings and cautions are mainly limited to the features of the NOVOS design. Modification or misuse of the product can be dangerous. NOVOS Tıbbi Cihazlar disclaims any responsibility for the results of product changes or modifications, and the results that may result from the combination of this product with other products from NOVOS or other manufacturers, unless such combination is approved by NOVOS.

	The use of this device requires continuous observation of the baby by trained medical personnel in order to provide immediate corrective action in situations involving risk of injury to the patient.

1.1.1. Patient Monitoring

Operators of this resuscitation system should recognize their responsibilities in selecting appropriate safety monitoring that provides adequate information on equipment performance and patient condition. Patient safety can be achieved through a wide range of different tools, from electronic monitoring of equipment performance and patient status to simple and direct observation of clinical findings. The responsibility for selecting the best patient monitoring level rests solely with the operator of the equipment.

1.2. Limitation of Liabilities

NOVOS has liabilities in the production, sale (activities), installation, promotion, use, application and product production guarantee of goods etc. These liabilities are subject to and are limited to the specific terms described in this manual. Circumstances that void the warranty, negligence that may occur independently of NOVOS, product violation, etc. limit the liability of NOVOS regardless of whether it was the fault of NOVOS and regardless of the manner in which the fault occurred. NOVOS shall not assume any liability for compensation for damages arising from or related to the products and for the buyer's liabilities to third parties; the buyer shall not have any right to claim compensation for these damages.

1.3. Usage Restrictions

Before using this device, it is important to know, understand and correctly apply the safety measures to be applied. The precautions mentioned below are intended to prevent a possible risk of injury to the patient or the device operator who will be treated with the radiant heater, and to guarantee efficient use of the device.

1.3.1. Warnings on Possible Physiological Effects

1.3.1.1. Indications, Contraindications and Side Effects

Indications are as follows:

- Hypoxemia / hypoxia
- Low apgar score
- Heart rate lower than 100 per minute
- Diaphragmatic hernia

Counterindications are as follows:

- Blood clot in the vein
- Uncontrolled blood loss

No side effect of the product.
Incorrect, longer than necessary and multiple intubation attempts may have adverse physiological effects.

1.3.2. Warnings for the Use of the Device

	The presence of oxygen increases the risk of combustion. When using the device, make sure that no explosive or flammable material is in the environment.
	Read the entire manual before using the device. The device should only be used by trained medical personnel who are aware of the benefits and risks of this device.
	Make sure that the patient circuit is not mixed or tangled with other cables to reduce the risk of chocking of the baby or cable entanglement and to avoid jamming of limbs or airway.
	In in-hospital transport, a stabilizer should be used to keep the device stable in order to prevent the device from being affected by vibration and bad roads.
	The device is connected only to the air, oxygen or a mixture of air and oxygen with adjustable gas flow.
	Make sure that the Easypuff device is at a distance from the baby that the patient circuit can easily reach and resuscitation can be performed easily.
	Before each use, make sure that the device is functionally working and complete.
	The intended use of the device is not suitable for ambulance.
	NOVOS cannot guarantee or support the safety performance of third party accessories. Use only original parts and accessories of NOVOS. The use of unapproved parts and accessories can cause serious damage to the patient and the device.
	Make sure that open flames, flammable anesthetics, and cleaning agents that may cause burns are not in the same environment with the device while the device is in use.
NOTE:	This device is also referred to as a “T-piece resuscitator” in terminology.

1.4. Warranty

All NOVOS products are warranted against manufacturing, workmanship and assembly defects for 12 months from the date of invoice. The conditions for this warranty are listed below;

1. Tax and import expenses of the shipped product are not covered by the warranty.
2. Repair, modification and changes made within the warranty period cannot be used to extend the specified warranty period.
3. The defect must have been caused by workmanship or material.
4. Only for problems caused by workmanship or materials, the parts replacement, reimbursement or repair of the product by NOVOS Tıbbi Cihazlar are possible. NOVOS Tıbbi Cihazlar reserves the right to apply one of the methods specified above, that is deemed appropriate based on the warranty claim.
5. NOVOS Tıbbi Cihazlar cannot be held responsible for the following conditions;
    a. Deterioration, wear or abuse of any component of the product
    b. Alteration, misuse, damage in transit, or modifications not approved by NOVOS Tıbbi Cihazlar or an authorized representative.
    c. Malfunctions arising from force majeure circumstances and other circumstances for which the manufacturer is not responsible.
    d. Malfunctions caused by voltage fluctuation.
    e. Malfunctions caused by inadequate or, if necessary, never provided customer service and maintenance.
    f. Normal wear and tear of working parts.
6. As for the warranty claim for the recovery of damage during transportation;
    a. The package/case should always be checked for any signs of damage.
    b. If any traces of damage are found, necessary records should be kept for proof of the damage.
    c. The carrier should be warned and the damaged product warranty claim form should be filled.
7. In any case, NOVOS Tıbbi Cihazlar is not liable for more than the original selling price.
8. The buyer guarantees that all services and maintenance are carried out in a timely manner by qualified personnel according to NOVOS service guidelines.

If these liabilities are not fulfilled, all warranty liabilities will expire. Warranty applications depend on the following:

1. If any malfunction occurs in the device or its parts, NOVOS or its authorized representative must be notified in writing immediately.
2. Defective devices and parts must be returned to NOVOS or an authorized factory center in accordance with the instructions of NOVOS service personnel.
3. As a result of evaluations, NOVOS or the authorized factory center must confirm that the warranty conditions cover this defect.
4. Written notice of the failure of the device or part must be received by NOVOS or authorized factory center 2 weeks before the end of the warranty period.

The above provisions belong to the sole warranty which is applicable and provided by NOVOS. It cannot be aimed to describe or explain the warranty status in any other way.

Dealers and representatives of NOVOS are not authorized to change these warranty conditions.

NOVOS Tıbbi Cihazlar.

2. Product Description

2.1. Usage Purpose

The Easypuff infant resuscitation device is an easy-to-use, gas-operated respirator that provides control and precise resuscitation of newborn babies in hospital rooms, nurseries and neonatal intensive care units.

The Easypuff is a baby breathing device where the user can determine the exact amount of air/oxygen mixture pressure that is transferred to the baby's lung.

2.2. Patient Population

This device is used in the treatment of babies between 0-28 days postnatal and for preterm babies whose adjusted age is fifty-two weeks.

2.3. Life Cycle

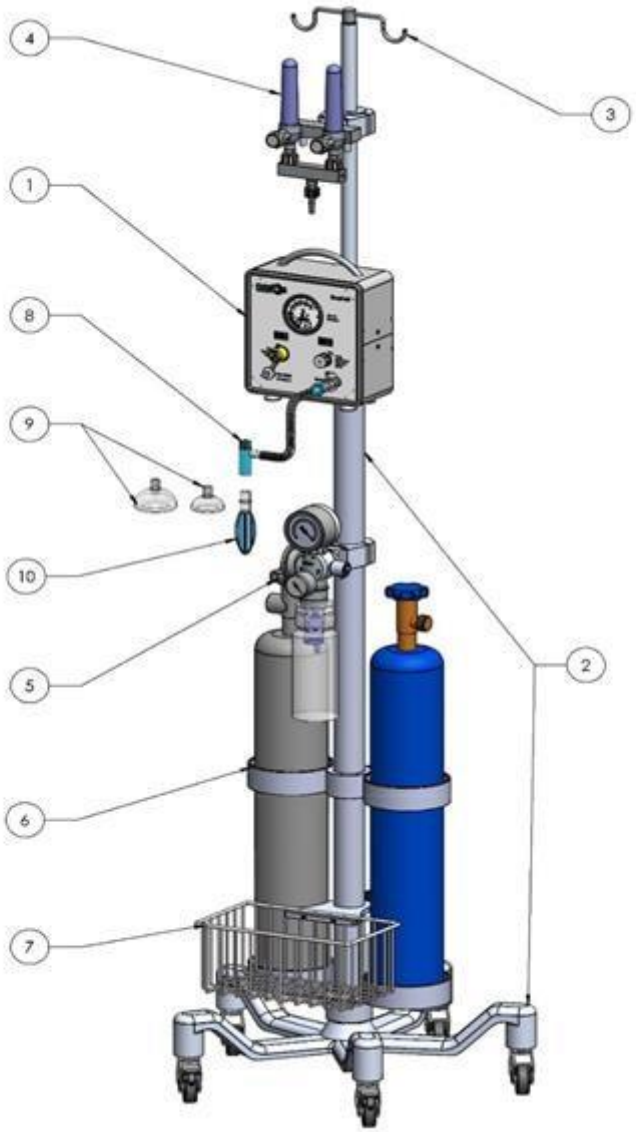
Easypuff can be used functionally for 7 years with regular authorized service intervention.

2.4. Target User Group

This device should be used by trained medical personnel (doctor, nurse, resuscitation specialist) who are experienced in resuscitation, know the benefits and risks of this device, and have the infrastructure to handle emergency situations.

2.5. Controls and Indicators

1	Handle	**5**	Manometer calibration hole
2	Manometer	**6**	PIP Adjustment Button
3	Maximum Pressure Relief Head & Control Button	**7**	T-Piece patient circuit control
4	Gas inlet connector	**8**	Ventouse



1	Easypuff	6	Tube Slot (optional)
2	Transport Trolley (optional)	7	Wire Basket (optional)
3	IV Pole (Optional)	8	T-Piece patient circuit
4	Blender (optional)	9	Mask
5	Vacuum Unit (Optional)	10	Test Lung

3.Preparation

The following procedure must be followed before each use to ensure the correct operation of the device.

1. Check the manometer.

   The manometer should show zero when there is no gas flow. If not, the manometer needs calibration (see the Service manual).
2. Connect to a gas supply.
   Examples for gas supply are shown below;

Oxygen Supply	
	
Flow-controlled Oxygen Cylinder	Wall Mounted Oxygen Flow Meter

Sources of Air / Oxygen Supply	
	
Flowmeter System	Air/Oxygen Blender

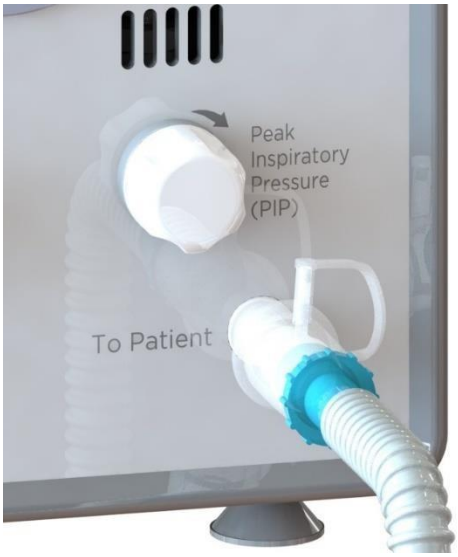
It is recommended to set the total flow to 8 l/min. If a flow meter system is used, make sure that the air/oxygen mixture does not exceed 15 l/min. For example, setting both the oxygen and air flows at 4 L/min will give a total flow rate of 8 L/min.

	Never use the device with a flow rate exceeding 15 l/min.

		Oxygen Concentration								
		21%	30%	40%	50%	60%	70%	80%	90%	100%
total Flow (l/min	1	Air - 1 O_2-0	Air - 0.87 O_2 - 0.12	Air - 0.75 O_2- 0.25	Air - 0.62 O_2- 0.37	Air - 0.5 O_2- 0.5	Air - 0.37 O_2- 0.62	Air - 0.25 O_2- 0.75	Air - 0.12 O_2- 0.87	Air - 0 O_2- 1
	2	Air - 2 O_2- 0	Air - 1.75 O_2- 0.25	Air - 1.5 O_2- 0.5	Air - 1.25 O_2- 0.75	Air - 1 O_2- 1	Air - 0.75 O_2- 1.25	Air - 0.5 O_2- 1.5	Air - 0.25 O_2- 1.75	Air - 0 O_2- 2
	3	Air - 3 O_2- 0	Air - 2.62 O_2- 0.37	Air - 2.25 O_2- 0.75	Air - 1.87 O_2- 1.12	Air - 1.5 O_2- 1.5	Air - 1.12 O_2- 1.87	Air - 0.75 O_2- 2.25	Air - 0.37 O_2- 2.62	Air - 0 O_2- 3
	4	Air - 4 O_2- 0	Air - 3.5 O_2- 0.5	Air - 3 O_2- 1	Air - 2.5 O_2- 1.5	Air - 2 O_2- 2	Air - 1.5 O_2- 2.5	Air - 1 O_2- 3	Air - 0.5 O_2- 3.5	Air - 0 O_2- 4
	5	Air - 5 O_2- 0	Air - 4.37 O_2- 0.62	Air - 3.75 O_2- 1.25	Air - 3.12 O_2- 1.87	Air - 2.5 O_2- 2.5	Air - 1.87 O_2- 3.12	Air - 1.25 O_2- 3.75	Air - 0.62 O_2- 4.37	Air - 0 O_2- 5
	6	Air - 6 O_2- 0	Air - 5.25 O_2- 0.75	Air - 4.5 O_2- 1.5	Air - 3.75 O_2- 2.25	Air - 3 O_2- 3	Air - 2.25 O_2- 3.75	Air - 1.5 O_2- 4.5	Air - 0.75 O_2- 5.25	Air - 0 O_2- 6
	7	Air - 7 O_2- 0	Air - 6.12 O_2- 0.87	Air - 5.25 O_2- 1.75	Air - 4.37 O_2- 2.62	Air - 3.5 O_2- 3.5	Air - 2.62 O_2- 4.37	Air - 1.75 O_2- 5.25	Air - 0.87 O_2- 6.12	Air - 0 O_2- 7
	8	Air - 8 O_2- 0	Air - 7 O_2- 1	Air - 6 O_2- 2	Air - 5 O_2- 3	Air - 4 O_2- 4	Air - 3 O_2- 5	Air - 2 O_2- 6	Air - 1 O_2- 7	Air - 0 O_2- 8
	9	Air - 9	Air - 7.87 O_2- 1.12	Air - 6.75 O_2- 2.25	Air - 5.62	Air - 4.5	Air - 3.37	Air - 2.25	Air - 1.12	Air - 0
	10	Air - 10 O_2- 0	Air - 8.75 O_2- 1.25	Air - 7.5 O_2- 2.5	Air - 6.25 O_2- 3.75	Air - 5 O_2- 5	Air - 3.75 O_2- 6.25	Air - 2.5 O_2- 7.5	Air -1.25 O_2- 8.75	Air - 0 O_2- 10
	11		Hava - 9.62 O_2- 1.37	Hava - 8.25 O_2- 2.75	Air - 6.87 O_2- 4.12	Air - 5.5 O_2- 5.5	Air - 4.12 O_2- 6.87	Air - 2.75 O_2- 8.25	Air -1.37 O_2- 9.62	
	12			Air - 9 O_2- 3	Air - 7.5 O_2- 4.5	Air - 6 O_2- 6	Air - 4.5 O_2- 7.5	Air - 3 O_2- 9		
	13			Air - 9.75 O_2- 3.25	Air - 8.12 O_2- 4.87	Air - 6.5 O_2- 6.5	Air - 4.87 O_2- 8.12	Air -3.25 O_2- 9.75		
	14				Air - 8.74 O_2- 5.24	Air - 7 O_2- 7	Air - 5.24 O_2- 8.74			
	15				Air - 9.36 O_2- 5.61	Air - 7.5 O_2- 7.5	Air - 5.61 O_2- 9.36			

⚠	When connecting the gas supply to Easypuff, please be careful not to damage the gas inlet. A slight force will be enough to properly insert the connector.

3. Attach T-Piece Circuit



- Connect the test balloon to the T-Piece Circuit, then connect the circuit to the gas outlet port.
- Attach the test lung to the T-Piece Circuit. (Before use, check for signs of damage such as changing the color of the test lung)

4. Check flow settings.

- Set the gas supply at the desired flow rate between 5-15 l/min.
- 8 l/min is the recommended flow rate.

Note: Make sure that the oxygen concentration of the Oxygen/Air supply is monitored using the oxygen analyzer or using the preset oxygen/Air flow rate chart.

5. Check the maximum pressure.

PEEP Head

- Close the PEEP head using your thumb and turn the PIP control fully clockwise until the knob no longer rotates.

*PEEP: Positive end-expiratory pressure ** PIP: Peak inspiratory pressure

- Remove the protective cap and adjust the maximum pressure control knob to set the desired maximum pressure.

Note:

The factory setting for the Maximum Pressure Discharge is 40 cmH2O [mbar].

- The Max Pressure Relief valve is like the total limit on the attainable circuit pressure. A pressure above 40 cmH2O [mbar] cannot be reached unless the Max Pressure Relief valve is adjusted.

6. Set PIP Value

PIP (Peak Inspiratory Pressure) indicates the maximum pressure during breathing. It is not evaluated according to the weight of the baby, but according to the rise and fall of the chest. It is adjusted by closing the PEEP head and turning the PIP control knob counterclockwise until the desired PIP value is set.

7. Set PEEP Value

PEEP (Positive End Expiratory Pressure) is to keep the airway pressure above atmospheric pressure at the end of respiration. It provides alveolar opening, prevents the alveoli from being closed again and allows the fluid to move from the alveoli to the interstitium. After removing your thumb from the PEEP head, you can adjust the PEEP value by turning the PEEP head.

4.Operating

- Adjust the gas supply and oxygen concentration at the desired flow rate (5-15l/min).

⚠	The device should only be used after the correct pressure is set. Do not use the device on the patient before making sure that the pressure is set.

- Select an appropriately sized neonatal breathing mask and connect it to the T-Piece circuit. Place the mask over the baby's mouth and nose or connect the T-Piece to the endotracheal tube.

- Resuscitate by placing your thumb over the PEEP head and pulling your thumb to allow breathing.

5.Routine Cleaning and Maintenance

5.1. Cleaning

T-Piece circuit and masks are "disposable" products. Do not clean and reuse them. If necessary, the outer surface of the gas supply line can be cleaned with isopropyl alcohol.

Clean the case of the device with a dry soapy cloth and soapy water. Rinse and dry. You can also wipe the exterior surfaces with isopropyl alcohol.

5.2. Maintenance

Under normal conditions of use, Easypuff requires minimal service and maintenance. It is recommended to calibrate the manometer once a year.

5.3. Disposal of Device

When the device has reached the end of its service life, dispose of the device according to the local waste disposal regulations in accordance with the medical waste regulation.

6.Troubleshooting

6.1. Fast Troubleshooting Guide

Problem	Solution
PIP and PEEP values may not reach preset values.	• Check that the flow rate is between 8-10 lpm. • Check the lung test for possible damage. • Check the lung test, T-Piece circuit and gas supply line.
	If problem continues; • Check that the manometer shows zero when there is no gas flow. • Check that the maximum pressure relief is set correctly at 40cmH2O.

7. Annexes

7.1. Technical Specifications

7.1.1. Dimensions and Weight

Height	26 cm
Width	20 cm
Depth	13 cm
Weight	1.5 kg

7.1.2. General Properties

Manometer Range	-20 / 80 cmH_2O
Maximum Pressure	Up to 5 - 70 cmH_2O
Peak Pressure (PIP)	0-70 cmH_2O @ 8 l/min
PEEP Pressure	1-10 cmH_2O @ 8 l/min
Gas Intake Range	5 – 15 l/min
Oxygen concentration	0-100 % (depending on gas amount)
Working time (400 lt cylinder)	50 min (8 l/min)
Recommended Body Weight	Up to 10 kg

7.1.3 Inspiration Peak Pressure

@ 5 l/min	2-70 cmH_2O
@ 8 l/min	3-72 cmH_2O
@ 10 l/min	4-73 cmH_2O
@ 15 l/min	8-75 cmH_2O

7.1.4 Operating Conditions

Temperature	(-18) / 41 °C
Humidity	20 - 90%
Pressure	800 / 1060 mbars

7.1.5. Storage Conditions

Temperature	(-20) - 60 °C
Humidity	5-95%
Pressure	800 / 1060 mbars

7.2. Compatibility

Document Published Institution/ Organization	Acceptance Date	Document Name / Title
TSE	12/9/2016	TS EN ISO 15223-1 / Medical devices - Symbols to be used in medical device labels, labeling and information to be conveyed- Part 1: General requirements
TSE	12/17/2013	TS EN ISO 14971 / Medical devices - Application of risk management to medical devices
TSE	3/29/2011	TS EN ISO 10993-1 / Biological evaluation of medical devices - Part 1: Evaluation and testing in a risk management process
TSE	10/23/2015	TS EN 62366-1 / Medical devices - Part 1: Application of usability technique to medical devices
European Commission	06.2016	MEDDEV 2.7.1 / Clinical evaluation: Guide for manufacturers and notified bodies
European Commission	01.2013	MEDDEV 2.12.1 / Guidelines on a Medical Devices Vigilance System
European Commission	01.2012	MEDDEV 2.12.2 / Post Market Clinical Follow-up studies
ISO	2006	ISO 10651-5 / Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 5: Gas-powered emergency resuscitators

7.2.1. Compliance Directive

Council Directive 93/42/EEC of 14 June 1993 on medical devices (1993-07-12 OJ L L 169/1)

The Medical Devices Directive (Council Directive 93/42/EEC of 14 June 1993 on medical devices, OJ L 169/1 of 1993-07-12 [1]) aims to harmonize the laws related to medical devices within the European Union. The MD Directive is the 'A New Approach' Directive, in order for a manufacturer to legally place a legal medical device on the European market, the requirements of the MD Directive must be fulfilled. Manufacturers' products meeting the 'harmonized standards' [2] have the presumption of conformity with the Directive. Products that comply with the MD Directive must bear the CE mark. The Directive was last revised by a review according to 2007/47/EC. Compliance with the revised directive became mandatory on 21 March 2010.

CE 1984

7.3. Trademark Registrations

Easypuff™ is a commercial product of Novos Tıbbi Cihazlar Sanayi ve Ticaret İthalat ve İhracat Limited Şirketi.

7.4. Manufacturer

Novos Tıbbi Cihazlar Sanayi ve Ticaret İthalat ve İhracat Limited Şirketi

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