

भारतसरकार/Government of India स्वास्थ्य और परिवार कल्याण मंत्रालय/ Ministry of Health and Family Welfare प्रधानमंत्रीस्वास्थ्यसुरक्षायोजना/PMSSY

अखिल भारतीय आयुर्विज्ञान संस्थानAll India Institute of Medical Sciences मंगलगिरि, आंध्रप्रदेश Mangalagiri, Andhra Pradesh

F No.: AIIMS MG/Procurement/06/Ambu Bags

Date: 13-07-2022

CALL FOR OBJECTION

AIIMS Mangalagiri has a requirement of AMBU MARK IV RESUSCITATORS (PEDIATRICS AND ADULT). In this regard comments/objection, if any is invited before declaring the article as proprietary in nature.

In this regard, the proposal submitted by M/s ALLIANCE MEDICAL SYSTEMS WEST MARREDPALLY, SECUNDERABAD, TELANAGANA a wholly owned subsidiary of M/S AMBU A/s, BALTORPBAKKEN 13, DK-2750 BALLERUP, DENMARK (A Sole manufacturer/agents) along with Proprietary Article Certificate are attached and duly uploaded on Institute website for open information to submit objections/comments, if any from any manufacturer/supplier before declaring the article of the said equipment/items to be procured as proprietary.

The objections/comments should be sent to the Procurement Section, Admin Building, 2nd floor, Room No. 236, AIIMS Mangalagiri, Guntur, Andhra Pradesh 522503 in a sealed envelope with the above reference on or before 23/07/2022, 12:00 Hrs, failing which it will be presumed that any other manufacture/vendor is having no objections/comments to offer and the case will be decided on merits.

F I/c (Procurement)
For Director, AIIMS Mangalagiri

Enclosure:

- 1. PAC of Departments
- 2. PAC of Manufacturer
- 3. Manufacturer Authorization Letter
- 4. Technical Specification sheets.

P-3 FORM

(To be attached with P-2 form for Proprietary items)

AIIMS, Mangalagiri

PROPRIETORY ARTICLE CERTIFICATE

It is certified that the items AMBU MARK-IV Baby Resuscitators (Pediatrics) required in the P-2 form should be purchased from M/s AMBU A/s, Baltorpbakken 13, DK - 2750 Ballerup, Denmark. To the best of my knowledge M/s, A/s, Baltorpbakken 13, DK - 2750 Ballerup, Denmark are the sole manufacturer/ agents of the sole manufacturers.

Similar items manufactured by other firm(s) shall not be suitable for our purpose for the following reasons:

- Self inflating double wall bag with built in pressure limitation technology, so that you can never push too hard.
- 2. Material of the bag is 100% latex free.
- 3. Single shutter valve system allows to view and manage airflow to patient.
- 4. Bag volume : AMBU MARK-IV Baby Resuscitators (Pediatrics) (300 ml)
- 5. Weight: AMBU MARK-IV Baby Resuscitators (Pediatrics) (190 gm)
- 6. Dimension: AMBU MARK-IV Baby Resuscitators (Pediatrics) (265 x 85 mm)

(Sign of Indenter)

Date: 7-1-2022

Designation:

Dr. VAMSIDHAR CHAMALA

Department:

KMC Regd. No : 81249 Asst. Professor Dept. of Anesthesiology AIIMS, MANGALAGIRI

Mukah In path

HOD, Department of Anesthesiology
All India Institute of Medical Sciences

Signature of Head of Department/Sectioniangal

N.B.. The indenter before recording the above certificate should satisfy himself that the article is genuinely of proprietary nature manufactured under patent laws.

P-3 FORM

(To be attached with P-2 form for Proprietary items)

AIIMS, Mangalagiri

PROPRIETORY ARTICLE CERTIFICATE

It is certified that the items AMBU MARK IV RESUSCITATOR (ADULT) required in the P-2 form should be purchased from M/S AMBU A/S, Baltorpbakken 13, DK - 2750 Ballerup, Denmark. To the best of my knowledge M/S, A/S, Baltorpbakken 13, DK - 2750 Ballerup, Denmark is the sole manufacturer of Ambu Mark IV (Adult) Reusable Manual Resuscitator.

Similar items manufactured by other firm(s) shall not be suitable for our purpose for the following reasons:

- 1. Self inflating double wall bag with built in pressure limitation technology, so that you can never push too hard.
- 2. Material of the bag is 100% latex free.
- 3. Single shutter valve system allows to view and manage air flow to patient.

(Sign of Indenter)

Date: 7/7/22

Design Qui UPPARA KADIYALA RAKESH (Regd.No:APMC 67506) MBBS, MD **Assistant Professor**

Department of General Medicine All India Institute of Medical Sciences Mangalagiri, Andhra Pradesh

V. Roed All India Institute of Medical Sciences Mangalagiri, Andhra Pradesh

Signature of Head of Department/Section

N.B.. The indenter before recording the above certificate should satisfy himself that the article is genuinely of proprietary nature manufactured under patent laws.



Date: 16th April, 2019

Proprietary Article Certification

To Whom It May Concern:

We hereby confirm that M/S Ambu A/S, Baltorpbakken 13, DK-2750 Ballerup, Denmark is the sole manufacturer of Ambu® Mark IV Adult and Ambu® Mark IV Baby Reusable Manual Resuscitator.

The only device of its kind, Ambu® Mark IV reusable manual resuscitator, has following features that are unique and proprietary:

- Self-Inflating Double wall bag with built-in pressure limitation technology, so that you can never push too hard.
- 100% Latex free material of bag.
- Unique Single Shutter-Valve system allows to view and manage airflow to patient.
- Bag Volume: Ambu® Mark IV Adult (1300ml) and Ambu® Mark IV Baby (300ml)
- Weight: Ambu® Mark IV Adult (415 gm) and Ambu® Mark IV Baby (190 gm)
- Dimension: Ambu® Mark IV Adult (275 x 135 mm) and Ambu® Mark IV Baby (265 x85 mm)

Ambu® Mark IV Resuscitator is intended for manual pulmonary resuscitation and emergency respiratory support.

The Device is 510K USFDA certified.

For Ambu A/S

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Date: 25th June 2022

To,

The Director

All India Institute at Medical Sciences,
Mangalagiri, Guntur,

Andhra Pradesh 522501.

Sub: Authorization Letter for Official Representation of AMBU.

Dear Sir / Madam,

We A/s Ambu who are established and reputed manufacturer of various medical devices having factories at Noblesville, Xiamen and Penang, hereby authorized M/s Alliance Medical Systems, Plot No. 22, # 3-13-131, Lalitha Nagar Colony, West Marredpally, Secunderabad, Telanagana - 500 026, to collect document, submit the bid and subsequently negotiates, sign the contract, raise invoice, collect payment and provide services to your esteemed organization on behalf of us for the below mentioned products manufactured by us.

1) Ambu MARK IV (both Adult and Baby Sizes).

We further confirm that no company or firm or individual other than M/s Alliance Medical Systems, is only authorized to quote, negotiate sale and supply above mentioned products to your esteemed organization.

Validity of this authorization letter will be till the tender last or till further notice.

Assuring you best of our services.

Yours Faithfully, For Ambu India Pvt. Ltd

11:33

B Sudheendra Kumar Business Manager – South India & Sri Lanka

CIN: U74999DL2014FTC330665

TECHNICAL SPECIFICATIONS OF AMBU MARK-IV Baby Resuscitators (Pediatrics)	
Application	Pulmonary resuscitation of neonates, infants and children with a body weight of up to 20 kg (approx. 4-5 years)
Maximum volume delivered	300 ml
Length x diameter (including patient valve)	265 mm x 85 mm
Weight of the resuscitator (with patient valve, without oxygen reservoir and mask)	190 g
Maximum frequency of ventilation	Depends on the tidal volume used. The rate of expansion of the bag is sufficiently fast for all frequencies recommended for practical use
Dead space	< 6 ml
Inspiratory resistance	- at 50 l/min -0.37 kPa (-3.7 cm H ₂ O) - at 5 l/min -0.05 kPa (-0.5 cm H ₂ O)
Expiratory resistance	- at 50 l/min 0.45 kPa (4.5 cm H ₂ O) - at 5 l/min 0.06 kPa (0.6 cm H ₂ O)
Maximum attainable delivery pressure	With compliance of 0.01 l/kPa Approx. 11.5 kPa (115 cm H ₂ O)
Pressure-limiting system .	Pressure-limiting valve opening pressure approx. 4 kPa (40 cm H ₂ O). If the pressure-limiting valve is overridden, the elasticity of the outer cover of the bag limits the airway pressure to approx. 4.5 kPa (45 cm H ₂ O) when squeezing the bag normally with one hand

Application	NS OF AMBU MARK IV RESUSCITATORS Pulmonary resuscitation of adults and children with a
Application	body weight of more than approx. 15 kg (3 years)
Maximum volume delivered	1300 ml
Length x diameter (including patient valve)	275 mm x 135 mm
Weight of the resuscitator (with patient valve, without oxygen reservoir and mask)	415 g
Maximum frequency of ventilation	Depends on the tidal volume used. The rate of expansion of the bag is sufficiently fast for all frequencies recommended for practical use
Patient connector	22/15 mm (ISO)
Expiration connector (for PEEP valve attachment)	30 mm male (ISO)
Dead space	< 5 ml
Inspiratory resistance	-at 50 L/min -0.35 kPa (-3.5 cm H2O)
Expiratory resistance	- at 50 L/min 0.26 kPa (2.6 cm H2O)
Maximum attainable delivery pressure	With compliance of 0.2 l/kPa Approx. 10 kPa (100 cm H2O)
Pressure-limiting system	The elasticity of the outer cover of the bag limits the airway pressure to approx. 7 kPa (70 cm H2O) when squeezing the bag normally with one hand
Bag reservoir volume	1500 ml
Application temperature	-18° C to 50° C (0° F to 122° F)
Storage temperature	-40° C to 70° C (-40° F to 158° F)
Inspiratory resistance of the oxygen reservoir bag (without supply of oxygen)	- at 50 l/min -0.1 kPa (-1.0 cm H2O) - at 5 l/min -0.01 kPa (-0.1 cm H2O)