9.1. General information.

Rubber medical products and *items for medical care* are intended for nursing and carrying out some medical procedures (administration of drugs or liquids) for hardly sick patients requiring strict bed rest.

Depending on design features rubber goods are subdivided into:

hollow ones (hot-water bottles, ice-bags, rings and bedpans, syringes, irrigating vessels, uterine rings, balloons and bellows);

tubular elastic ones (tubes for drainage, blood transfusions, flatus tubes, catheters and probes);

elastic items for narcosis and artificial ventilation (air pipes, intubation tubes, oral-nose narcosis masks);

latex products (surgical and anatomic gloves, finger-stall, disperser hoods for medical pipettes, baby's dummies).

Depending on methods of manufacturing rubber goods are divided into:

non- molded (vulcanized rubber sheets stuck with rubber adhesive, for example, bedpan rings);

molded (products obtained by pressing or extrusion into moulds, for example, hot-water bottles, ice-bags, syringes, etc.);

seamless (products obtained by method of extrusion or forcing, for example, tubes, bandages, or by method of mould dipping into latex, for example, gloves, finger-stalls, condoms, etc.).

Technological process of rubber goods manufacture consists of three stages: preparation of raw material, preparation of rubber stock, manufacturing of a product. Basic components of rubber stock include: raw rubbers (natural and synthetic), vulcanizing agents (e.g. sulfur), vulcanization accelerators (altax), activators (for example, calcium stearate), age resistors or stabilizers (more often ionol), fillers (aerosil, chalk, etc.), plastifiers (acid ethers), dyes. Latex systems contain aqueous or other dispersion of rubber gum, emulsifying agents, stabilizers and stiffeners.

For rubber medical products the following **technical** and **sanitary-hygienic requirements** are showed:

- ✓ stability of products during service period;
- ✓ certain physical-mechanical properties (hardness, elasticity, elastic modulus);
- ✓ absence of ageing signs (cracks, stickiness, decolourization, etc.);
- ✓ absence of foreign substances;
- ✓ tightness;
- ✓ completeness;
- ✓ resistance against multiple disinfection or sterilization.

Disinfection of rubber goods, such as hot-water bottles, gloves, catheter, probes, tips, in medical establishments is carried out by boiling in sterilizer during

15 minutes (after cooling boiling is retried twice) or by dipping into 1 % solution of toluene sulphonchloramide, 3% hydrogen peroxide by itself or with addition of 0,5 % detergent solution. Sterilization is carried out in steam sterilizers or by storage of rubber products in 5 % carbolic water with glycerin.

Shelf-life of rubber goods depends on composition of rubber stock, product design, method of vulcanization, conditions of storage, mode of operation, etc.

Packing and transportation.

Products are packed into polyethylene parcels, cardboard boxes or cases of corrugated cardboard. In each box not more than 10 items should be put, into cases - not more than 50 items.

Packed rubber medical products are transported in covered vehicles at temperature from -50 up to +50 °C. During transportation products should not be exposed to fat oils, solvents, acids, alkalis and other substances decomposing rubber.

Storage of rubber goods.

Products should be stored packed according to requirements of corresponding standards and technical specifications.

In premises for storage of rubber goods it is necessary to provide:

- ✓ protection from light, especially from direct solar beams, high (more than 20°C) and low (less than 0°C) temperatures; drafts, mechanical ventilation; mechanical effects (compressing, bend, twisting, elongation, etc.);
- ✓ relative humidity of air not less than 65 % and not more than 80 % (for prevention of drying, deformation and loss of elasticity);
- ✓ prevention from action of chemicals (iodine, chloroform, ammonium chloride, lysol, formalin, acids, organic solvents, fat oils, alkalis, toluene sulphonchloramide B);
- ✓ storage at distance not less than 1 m from heating devices.

Premises for storage of rubber goods are located apart from solar side, better in semibasement dark premises. To maintain increased humidity in dry premises it is recommended to carry out humidifying.

In premises, cases it is recommended to put vessels with ammonium carbonate which promotes preservation of rubber elasticity.

For storage of rubber goods premises should be equipped with cases, boxes, shelves, racks and other necessary stock providing easy approach.

In premise for storage of rubber goods it's necessary to use all its volume completely. This prevents harmful influence of air oxygen. Rubber products should not be stacked in several layers as items placed in lower layers shrink and stick together. Cases should have smooth internal surface and tightly closed doors.

The design of cases depends on kind of rubber goods stored therein – the cases intended:

- for storage of rubber goods in lying position (bougies, catheters, ice-bags, gloves) – it is recommended to equip them with sliding boxes to facilitate placing items by all their length, loosely, without bends, flattening, twisting;
- for storage of products in hanged position (bandages, probes, irrigation tubes) – such cases are equipped with hangers located under cover of a case. Hangers should be demountable together with hanged items.

Rubber goods are arranged in storehouses by their names and shelf-lives, each batch is attached with a label containing indication of the product name and its shelf-life.

More attention should be paid for some kinds of rubber goods which require special storage conditions:

- bedpan rings, hot-water bottles, ice-bags should be stored with plugs and slightly inflated;
- demountable rubber parts of devices should be stored separately from parts made of other materials;
- products, very sensitive to atmospheric factors - elastic bougies, catheters, gloves, finger-stalls, rubber bandages – are stored turned, dusted with talc by all length;
- rubberized fabric (unilateral and bilateral) is stored separately from chemicals in horizontal position in rolls hanged on special racks, but not more than five rolls stacked on evenly planed shelves of racks;
- elastic products - bougies, catheters, probes, having ethylcellulose varnish coating are stored in dry premises (unlike rubber). Signs of their ageing are softening and stickiness of surface. Such products should be withdrawn and removed.

Rubber goods should be inspected time to time. Items which start to lose elasticity should be recovered according to requirements of the normative documentation.

Rubber gloves if they became hardened and fragile are recommended to put, without straightening, for 15 minutes into warm (40°C) 5% ammonia solution, then for 15 minutes into warm (40°C) water with 5% of glycerin. Gloves will become elastic again. Liquid is removed from surface of a product with soft cloth and an item is then dusted with talc.

Assortment of rubber goods and items for medical care.

Hot-water bottles are intended for local warming of a body, washing and syringing. Electric, rubber and thermochemical hot-water bottles are produced.

Hot-water rubber bottles depending on their purpose are divided into two

types: **A** - for local body warming and **B** - combined type used for local warming, washing and syringing. Hot-water bottle of type A consists of a body with built-in liner, has a screwed stopper, gum strip and loop. The type B is completed with screw valve having through hole, rubber tube not less than 1400 mm in length and 8 mm in diameter, rotary valve and three disposable tips (for babies, adults and uterine).

Hot-water bottles are produced of three capacities - 1, 2 and 3 *l*, with hanging loop of two versions - bulging and indrawn. Number of a hot-water bottle corresponds to its capacity.

Should be stored hanged by loop. A warranty storage period of hot-water bottles is 3,5 years, warranty period of operation - 2 years.

Rubber irrigation cup is used in domestic and hospital conditions for syringing and washing. It is flat reservoir with a wide throat which is jointed to a rubber tube with fitting pipe. The tube is supplied with hard tip and ebonite or plastic rotary valve.

Cups are produced by molding and of three capacity sizes 1 *l* (№1); 1,5 *l* (№2) and 2 *l* (№3). To check integrity a cup filled completely with water is hanged for 8 hours and then by loss of water its quality is evaluated. A cup should not have any leakage, especially in joint of tube and near valve.

Syringes are used for washing of various canals and cavities (including wounds), in children's practice and in laboratory work. Big syringes are applied for enemas, medium ones – for ear washing, small ones - in laboratory work. Syringes are rubber pear-shaped balloons with elastic walls of various capacity with soft or solid tip of ebonite or plastic.

Syringes with a soft tip (type A) are produced in capacities of 15 (№ 1/2), 30 (№ 1), 45 (№ 1½), 60 (№ 2), 75 (№ 2½), 90 (№ 3), 120 (№ 4), 180 (№ 6) and 270 ml (№ 9).

Syringes with a solid tip (type B) are produced in capacities of 30 (№ 1); 60 (№1½); 90 (№ 2); 120 (№ 2½); 150 (№ 3); 180 (№ 4); 210 (№ 5); 240 (№ 6); 270 (№9) and 300 ml (№ 12).

Warranty period of storage is 1 year.

There are also polyvinylchloride (PVC) syringes with soft and solid tips. Warranty period for these syringes is 2 years from date of manufacture.

Rubber bellows and balloons are intended for air forcing, including dispersion of liquids with the help of sprayers.

Bellows differ from balloons in that they are supplied with two valves - soaking and forcing ones.

There are the following balloons manufactured:

- Rubber thick-walled balloons for medical apparatus (for device to measure arterial pressure, for electrocardiograph, for bronchoesophagoscope);
- Rubber balloons (with ebonite tip for blowing of ears; for dental surgery;

for drop-counters in drug preparation).

Rubber bellows are manufactured as double-balloon (type A) and single-balloon (type B), having one thick-walled balloon supplied with valves and tube.

Warranty period of storage is not more than 2 years.

Rubber ice bags are intended for local cooling of a body. Depending on purpose ice-bags are produced of six types (tab. 9.1).

Ice bags for common use are produced in three numbers (№ 1, № 2, № 3) with diameters of 150, 200 and 250 mm respectively. They can contain from 0,5 up to 1,5 kg of ice.

Table 9.1.

Classification of ice bags

Type of an ice bag	Purpose of an ice bag
I	For common use (№ 1, № 2, № 3)
	For special use:
II	For an eye
III	For a throat
IV	For an ear
V	For female heart
VI	For male heart

Warranty period of storage for ice-bags is 3,5 years from date of manufacture. Warranty period of operation - 3 years from date of sale through retail trading network, in medical establishments - 1,5 years.

Bedpan rings are used to prevent bedsores in patients. They are produced in three sizes (№ 1, № 2, № 3) with internal and external diameters accordingly: № 1 - 95/300 mm, № 2 - 130/380 mm, № 3 - 145/450 mm.

Uterine rings are intended for prevention of uterus fallout. They are produced in seven sizes - from 00 up to 5 - with external diameter 40, 55, 65, 68, 80, 90 and 100 mm. Rings should be elastic and become straightened immediately after compression. On their surface cracks, bubbles and ledges are not allowed.

Tubes of rubber and synthetic polymers are used for feeding and removal of liquids or gases from an organism and in laboratory practice. Depending on purpose tubes are produced: for blood transfusion, drainage, vacuum, for oxygen pillows, acoustical, connecting. Warranty period of their storage is 2 years.

Silicone medical tubes are applied for mounting of devices for synthetic blood circulation, transfusion of blood and pharmaceuticals, and also for drainages of various purpose. Silicone tubes can be clear and semitransparent. They are not stable against alkalis. Temperature mode of operation is from -90 up to 300°C. They withstand multiple (up to 100 times) heat sterilization. Tubes in diameter from 4 up to 18 mm with wall thickness from 1,5 up to 5 mm are available.

PVC tubes are produced in diameter from 0,4 up to 25 mm, with wall

thickness of 0,3-1,5 mm. They are applied in many medical devices as connecting units as they have high elasticity. They are transparent, do not cause harmful influence on a human body. For production of such tubes one can use plastics of the following grades: T-35, PM-1/42, PME 60-90, P-65ME, allowed by public health services.

Flatus tubes are used for removal of gases from rectum and sigmoid guts at meteorism. They are produced in ten sizes – № 22-№ 42 (even counts) in length of 50 and 75 cm.

Cylindrical catheters are intended for urine removal and washing of bladder. They are produced in eight sizes – № 8-№ 24 (even counts) in length from 38 up to 40 cm.

Catheter for bladder draining during postoperative period: large-head one by Petzer, with cruciform head by Maleko. They are produced in sizes № 12 up to № 40.

Duodenal tubes are applied to take an assay of bile from duodenal gut. They are produced with metal olive at the end and without it. Four ring-shaped marks on probes allow to control depth of its introduction. Sizes are from № 8 to № 22 and from № 12 to № 32 with length of 80, 90, 105, 120, 135 and 150 cm.

Gastric tubes are applied to take an assay of gastric juice, and also for washing of a stomach with the medical purpose. Sizes are from № 8 to № 24.

Intubation tubes are applied for gas narcosis and artificial ventilation. They are produced in two modifications: simple ones and with inflatable cup. Tubes are produced in thirteen sizes - № 11 - № 40.

Air lines are intended to maintain artificial ventilation. They are produced in two kinds - nasal and oral ones in diameter from 2,5 up to 10 mm with step of 0,5 mm – 16 sizes.

At acceptance of tubes, catheters, probes you should pay attention to their elasticity and quality of surface which should be smooth, without cracks.

Latex products.

Surgical gloves are used for aseptic operations, and also for manual inspection of infected bodies and tissues. Depending on palm width and size of wrist gloves are manufactured in the following sizes: № 8-10 – for men, № 1-7 – for women. Warranty period of storage is 1 year.

Anatomic gloves are applied at pathoanatomical openings and other anatomic operations for protection of doctor's hands. Strict requirements for hardness and tightness are stated for these gloves. Anatomic gloves differ from surgical ones by greater thickness of walls (up to 0,5 mm) and they are produced in three sizes: №7, 8, 9 with length of 275 mm. Warranty period of storage is 1 year.

Finger-stalls are intended for protection of hand fingers. They are produced in three sizes (63, 70 & 77 mm long and 24, 26 and 28 mm in semi-circle size). Wall thickness is 0,2-0,3 mm.

Items of medical care (nursing goods).

Medical oilcloths depending on their purpose are produced unilateral and bilateral having different hardness on basis of madapollam or polyester-viscose and cotton fabrics.

Rubberized-fabric oilcloth is used as impenetrable material for sanitary-and-hygienic purposes (in children's hospitals, maternity hospitals, in departments for hardly sick patients and other medical institutions).

Depending on a fabric - basis there are two kinds of oilcloth: A - on cotton basis and B - on basis of polyester-viscose or other synthetic fabrics of various light hues.

For quality evaluation physical-mechanical parameters are standardized: breaking weight (N or kgf), hardness (N or kgf), weight of 1 m^2. An oilcloth should not contain soluble compounds of lead, barium, mercury and arsenic. It should be water-proof, elastic, non-sticky, easily washable, withstand action of antiseptic agents. It is produced in rolls not more than 75 m long and not less than 0,75 m wide and in pieces 0,5 - 3 m long and not less than 0,7 m wide.

Warranty storage period for an oilcloth of A type is 24 months, those of B type– 26 months from manufacture date.

Bed oilcloths are produced also of vinyl plastic as a film 60-90 cm wide and 0,4-1 mm thick.

Compress oilcloth (compress plasticate) has thickness 0,05 - 0,15 mm and applied for hermetic sealing of a bandage and separation of its damp part from bandage and cotton wool. It is produced of light fabrics (lawn, thin calico), covered with rubber or polymer on one side, and with pitchy antifouling impregnation (more often linseed oil with colophony) – on another side. An oilcloth should not stick together at folding.

Abdominal supports – devices preventing passage of peritoneal organs through hernial gate, strengthening abdominal tension and supporting falling internal organs in normal position. Spring and springless abdominal supports are available. By purpose of application preventive (abdominal band, pre-natal, post-natal), medical and hernial abdominal supports are distinguished.

Hernial abdominal support is steel springing plate covered with soft leather or suede with special small pillows for pressure on area of hernial gate. Right-hand, left-hand and bilateral abdominal supports are available.

Abdominal unilateral support for inguinal hernias for adults is springing bandage made as skin belt with pear-shaped pillow filled with sawdust on one end. It has triangular shape and convex surface providing constant pressure upon hernial area. Right and left abdominal supports are available.

Abdominal bilateral support for inguinal hernias has pillows on both ends. There are abdominal supports for adults and for children.

Umbilical abdominal support is a suede belt with flat round pillow in the

middle. It has loops at the ends. With the help of laces it is tightened behind. Abdominal supports are produced for children and for adults.

Prenatal abdominal support is wide cotton belt with elastic bands for fastening of stockings and additional rubber-fabric elastic belts for supporting of a stomach. Each belt has some apertures for built-in hooks. It is produced in two versions: prenatal abdominal support facilitated (model T-11) and prenatal abdominal support with soft panel (model T-12). Bandages are produced in various sizes.

Post-natal abdominal support is intended for bearing after childbirth. It is longer than prenatal one.

Medical abdominal support is used under recommendation of a doctor during ptosis of interiors - stomach, intestines, kidneys (low bandages).

Medical cupping glasses are intended for static and kinetic vacuum-therapy (cup massage). They are round small glass vessels 30-70 cc in capacity with thickened smooth edges and dilated bottom. Edges of jars should be smooth, well fire-polished. The goods are supplied in individual package by 1, 4 and 8 pieces.

Breast pump - the device for withdrawing of breast milk. By operating mode they are divided into electric, water jet and manual ones.

Manual breast pump is a conic tube with a bell mouth on one end and elastic rubber balloon mounted on the opposite end. It is produced in two kinds: with glass receiver (packed individually) and with plastic receiver.

Mustard plasters are applied as topical irritant, warming and abstracting means. They are rectangular paper sheets 8x12,5 cm in size covered with defatted powder of black or sareptic mustard (Brassica juncea). Shelf-life is 1 year, after control tests - 6 additional months. Mustard plasters produced in 4-cell packages have shelf-life 2 years.

The first-aid set is produced as automobile and collective sets. They differ by range and quantity of drugs and products of medical purpose.

Body jackets are applied at myositis, lumbodynia, lumbosacral radiculitis, osteochondrosis, bone rarefication, infringement of bearing and deformations of backbone. Spinal supports for lumbar and thoracolumbar departments (of general purpose, stabilizing, classical) are produced in the following sizes: XS: 56-64 cm, S: 64-72 cm, M: 72-80 cm, L: 80-90 cm, XL: 90-100 cm, XXL: 100-110 cm.

Kneecaps are applied during rehabilitation period after traumas and surgery operations on knee joint, at moderate lateral instability, chronic incomplete dislocations of patella, osteoarthritis, knee joint bursitis, gonarthritis. The kneecaps are produced with armor, lateral tires and hinge, elastic and with an aperture; of the following sizes – XS: 28-30 cm, S: 30-33 cm, M: 33-36 cm, L: 36-39 cm, XL: 39-42 cm, XXL: 42-45 cm.

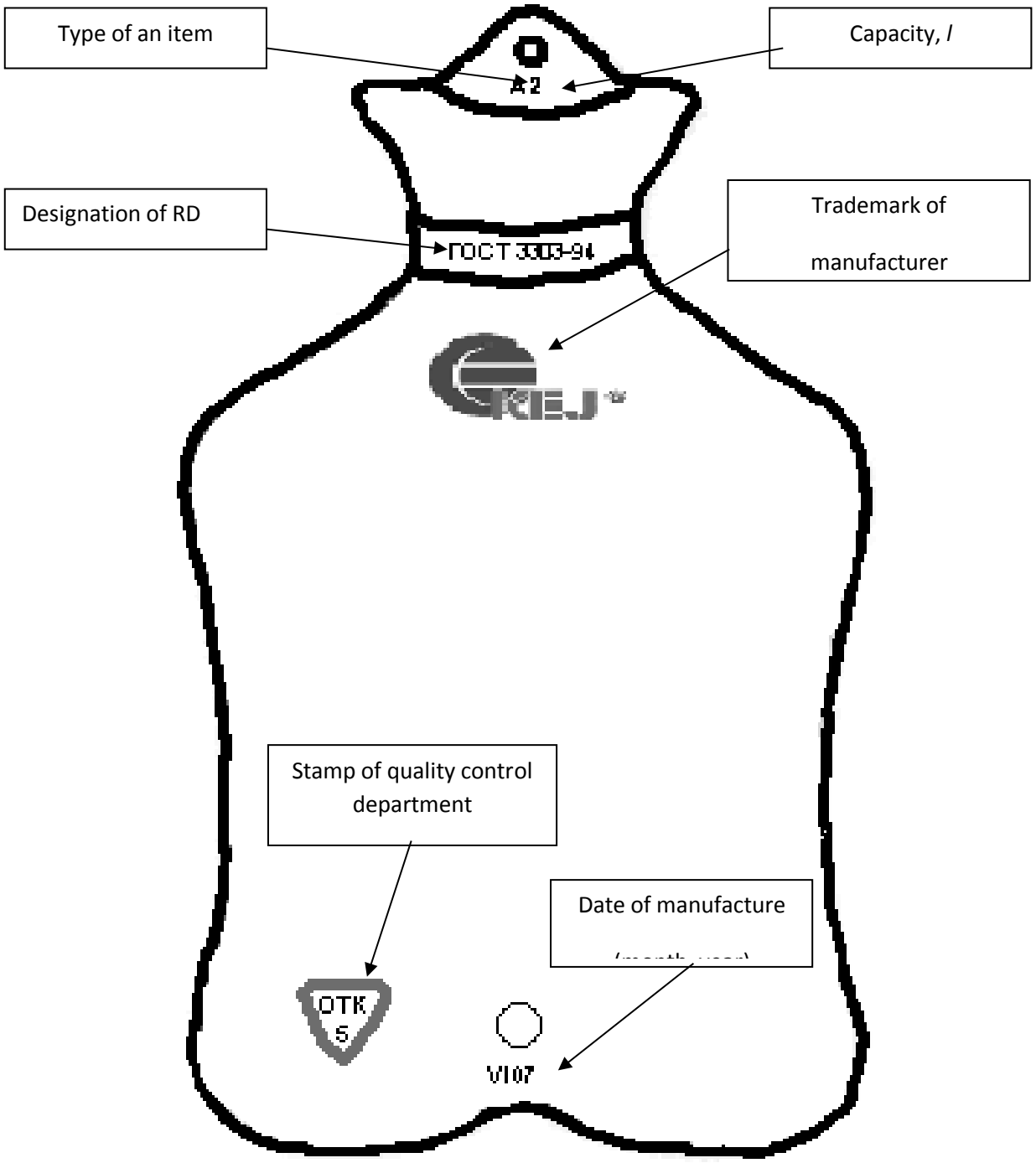
Urinals are used at urinary incontinence, nephrostomy, epicystostomy. They are produced of rubber, glass and plastic. Glass urinals should not have cracks, sharp scratched edges, mouth should be smooth.

Crutches - device facilitating movement at disease or damage of legs, foots or column and allowing to transfer loading from sick organs to hands. They are produced of hard wood grades or of metal. Two types of crutches are available: with hand - armpits support and with hand-forearm support. Crutches of the first type are usually folding, it's possible to change their height depending on patient stature, and crutches of the second type are non-folding, produced of metal by strict sizes. They have fixed horizontal support for a hand and on top end - an oval metal plate (armrest). The latter should be on level of the top third of forearm. The armrest and support for a hand are covered with leather.

Medical pipette is intended for instillation of drugs. It consists of glass body and rubber cap. Complete delivery set should contain: 1 pipette assembled (in individual package) or 200-400 items (in group package), retail container and label. Warranty shelf-life of pipettes is 1 year.

Bedpan is used for a toilet of bed patients (after surgical operations, cardiac infarction, etc.). They are produced as metal, enameled, faience and rubber vessels of various shapes (oblong, round).

9.2. Marking of rubber products (example).


Type of an item
Capacity, *l*
A2
Designation of RD
ГОСТ 3303-94
Trademark of manufacturer
Stamp of quality control department
Date of manufacture
OTK
5
V107