30.02 - Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products (+).

- Antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes :

3002.11 - - Malaria diagnostic test kits

3002.12 - - Antisera and other blood fractions

3002.13 - - Immunological products, unmixed, not put up in measured doses or in forms or packings for retail sale

3002.14 - - Immunological products, mixed, not put up in measured doses or in forms or packings for retail sale

3002.15 - - Immunological products, put up in measured doses or in forms or packings for retail sale

3002.19 - - Other

3002.20 - Vaccines for human medicine

3002.30 - Vaccines for veterinary medicine

3002.90 - Other

This heading covers :

(A) **Human blood** (e.g., human blood in sealed ampoules).

(B) **Animal blood prepared for therapeutic, prophylactic or diagnostic uses.**

Animal blood not prepared for such uses falls in **heading 05.11**.

(C) **Antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes.**

These products include :

(1) **Antisera and other blood fractions, whether or not modified or obtained by means of biotechnological processes.**

Sera are the fluid fractions separated from blood after clotting.

The heading covers, *inter alia*, the following products derived from blood (including vascular endothelial cells) : "normal" sera, human normal immunoglobulin, blood fractions and truncated variants (parts) thereof with enzymatic properties/activity, plasma, thrombin, fibrinogen, fibrin and other blood coagulation factors, thrombomodulin, blood globulins, serum globulins, and haemoglobin. This group also includes modified thrombomodulins and modified haemoglobins obtained by means of biotechnological processes, e.g., sothrombomodulin alfa (INN) and thrombomodulin alfa (INN), as well as cross-linked haemoglobins such as hemoglobin crosfumaril (INN), hemoglobin glutamer (INN) and hemoglobin raffimer (INN).

The heading further includes blood albumin (e.g., human albumin obtained by fractionating the plasma of whole human blood), prepared for therapeutic or prophylactic uses.

Antisera are obtained from the blood of humans or of animals which are immune or have been immunised against diseases or ailments, whether these are caused by pathogenic bacteria and viruses, toxins or allergic phenomena, etc. Antisera are used against diphtheria, dysentery, gangrene, meningitis, pneumonia, tetanus, staphylococcal or streptococcal infections, snake bite, vegetable poisoning, allergic diseases, etc. Antisera are also used for diagnostic purposes, including in vitro tests. Specific immunoglobulins are purified preparations of antisera.

The heading **does not cover** blood albumin not prepared for therapeutic or prophylactic uses (**heading 35.02**) or globulins (other than blood globulins and serum globulins) (**heading 35.04**). The heading also **excludes** medicaments which are not separated from the blood but which in some countries are described as "sera" or "artificial sera"; they include isotonic solutions based on sodium chloride or other chemicals and suspensions of pollen which are used against allergic diseases.

(2) **Immunological products, whether or not modified or obtained by means of biotechnological processes.**

Products used for diagnostic or therapeutic purposes and for immunological tests are to be regarded as falling within this product group. They can be defined as follows :

(a) **Monoclonal antibodies (MAB)** - specific immunoglobulins from selected and cloned hybridoma cells cultured in a culture medium or ascites.

(b) **Antibody fragments** – active parts of an antibody protein obtained by means of e. g., specific enzymatic splitting. This group includes inter alia single-chain (scFv) antibodies.

(c) **Antibody conjugates and antibody fragment conjugates** – conjugates which contain at least one antibody or an antibody fragment. The simplest types are a combination of the following :

(i) antibody – antibody;
(ii) antibody fragment – antibody fragment;
(iii) antibody – antibody fragment;
(iv) antibody – other substance;
(v) antibody fragment – other substance.

Conjugates of types (iv) and (v) include, for example, enzymes (e.g., alkaline phosphatase, peroxidase or betagalactosidase) or dyes (fluorescin) covalently bound to the protein structure, which are used for straightforward detection reactions.

This heading also covers interleukins, interferons (IFN), chemokines and certain tumor necrosis factors (TNF), growth factors (GF), hematopoietins and colony stimulating factors (CSF).

(D) **Vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products.**

These products include :

(1) **Vaccines.**

The most typical vaccines are prophylactic preparations of microbial origin containing either viruses or bacteria suspended in saline solutions, oil (lipovaccines) or other media. These preparations have usually been treated to reduce their toxicity without destroying their immunizing properties.

Other vaccines include recombinant vaccines, peptide vaccines and carbohydrate vaccines. These vaccines generally contain an antigen, a recognised part of an antigen or a gene coding for a recognised part of an antigen (peptides, recombinants or conjugates of protein and others). The "recognised part of an antigen" is the part of an antigen which triggers the immunological response in the organism. Many of these vaccines target a specific virus or bacterium. These vaccines are used for prophylactic or therapeutic purposes.

The heading also covers mixtures consisting of vaccines or toxoids (such as Diphtheria, Tetanus and Pertussis (DPT) vaccine).

(2) **Toxins** (poisons), toxoids, crypto-toxins, protoxins (e.g., topsalysin (INN)) and anti-toxins.

(3) **Cultures of micro-organisms (excluding yeasts)**. These include ferments such as lactic ferments used in the preparation of milk derivatives (kephir, yogurt, lactic acid) and acetic ferments for making vinegar; moulds for the manufacture of penicillin and other antibiotics; and cultures of micro-organisms for technical purposes (e.g., for aiding plant growth).

Milk or whey containing small quantities of lactic ferments is classifiable in **Chapter 4**.

(4) **Virus, human, animal and vegetable and anti-virus**.

(5) **Bacteriophage**.

The heading also includes diagnostic reagents of microbial origin, **other than** those provided for in Note 4 (d) to this Chapter - see **heading 30.06**. It **does not cover** enzymes (rennet, amylase, etc.) even if of microbial origin (streptokinase, streptodornase, etc.) (**heading 35.07**) **nor dead** single-cell micro-organisms (other than vaccines) (**heading 21.02**).

(E) **Diagnostic kits**.

Diagnostic kits are classified here when the essential character of the kit is given by any of the products of this heading. Common reactions occurring in the use of such kits include agglutination, precipitation, neutralization, binding of complement, haemagglutination, enzyme-linked immunosorbent assay (ELISA), etc. Malaria diagnostic kits based on monoclonal antibodies to pLDH (plasmodium lactate dehydrogenase) are for instance classified here. The essential character is given by that single component which governs to the greatest extent the specificity of the test procedure.

The products of this heading remain classified here whether or not in measured doses or put up for retail sale and whether in bulk or in small packings.

°
° °

Subheading Explanatory Note.

Subheading 3002.13

The unmixed immunological products of subheading 3002.13 may contain impurities. The term "impurities" applies exclusively to substances whose presence in the products results solely and directly from the manufacturing process (including purification). These substances may result from any of the factors involved in the process and are principally the following :

(a) Unconverted starting materials.

(b) Impurities present in the starting materials.

(c) Reagents used in the manufacturing process (including purification).

(d) By-products.