II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/523

of 7 April 2020

amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff as regards subheading 9021 10 10 (orthopaedic appliances)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff ([1]), and in particular Article 9(1)(e) thereof,

Whereas:

(1) Regulation (EEC) No 2658/87 establishes a goods nomenclature (hereinafter referred to as the 'Combined Nomenclature'), which is reproduced in Annex I to that Regulation.

(2) In the interest of legal certainty, it is necessary to clarify the classification of orthopaedic appliances of subheading 9021 10 10 of the Combined Nomenclature.

(3) In accordance with the judgment of the Court of Justice in Joined Cases C-260/00 to C-263/00 ([2]), the Harmonized System Explanatory Notes to heading 9021 and Note 6 to Chapter 90, orthopaedic appliances are defined as products specially designed for a particular orthopaedic purpose.

(4) In that judgment, the Court of Justice explained that orthopaedic appliances have a specific medical purpose in distinction to ordinary (simple) products that are for general use. The criteria for distinguishing orthopaedic appliances from ordinary products also include the method of manufacture, the materials of which they are made, their method of operation, their adjustability to the patient's specific handicaps.

(5) Note 6 to Chapter 90 provides that orthopaedic appliances serve either to prevent or correct bodily deformities or to support or hold parts of the body following an illness, operation or injury.

(6) Section (I) of the Harmonized System Explanatory Notes to heading 9021 provides examples of a number of orthopaedic appliances covered by the heading together with examples of products that are not covered by heading 9021. The product scope established by these explanatory notes is in line with the new Additional note.

([1]) OJ L 256, 7.9.1987, p. 1.
([2]) Judgment of the Court of Justice of 7 November 2002, *Lohmann and Medi Bayreuth*, Joined Cases C-260/00 to C-263/00, ECLI:EU:C:2002:637.

(7) For reasons of legal certainty, it is necessary to provide examples of medical purposes that certain products might serve which distinguish them from orthopaedic appliances that are designed for a particular orthopaedic purpose.

(8) For reasons of legal certainty, explanations should be provided on the method of operation (high degree of precision) of orthopaedic appliances that are meant to prevent further injuries or bodily deformities in distinction to ordinary products that are not considered to be designed with the same high degree of precision and, thus, are not able to prevent completely undesired movements.

(9) A new Additional note should therefore be added to Chapter 90 of Part Two of the Combined Nomenclature to ensure its uniform interpretation.

(10) The new Additional note is in line with Commission Implementing Regulation (EU) 2018/787 ([3]) classifiying an ankle bandage (so-called 'lace-orthosis'), with the existing Explanatory Notes to the Combined Nomenclature to subheading 9021 10 10, and reflects the established classification practice of the Member States.

(11) Regulation (EEC) No 2658/87 should therefore be amended accordingly.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Chapter 90 of Part Two of Annex I to Regulation (EEC) No 2658/87 is amended as follows:

(1) the heading 'Additional note' after note 7 is replaced by the heading 'Additional notes';

(2) the following Additional note is added:

'2. For the purposes of subheading 9021 10 10, the expression "orthopaedic appliances" means appliances which are specially designed for a particular orthopaedic purpose, in distinction to products that might be used for various purposes (for example, products for overstrained joints, ligaments or tendons caused by sporting activities, type writing, and products which simply alleviate pain in the defective or disabled part of the body, for example, caused by inflammation).

The "orthopaedic appliances" must completely prevent a specific movement of the defective or disabled part of the body (for example, joints, ligaments, tendons) in order to exclude further injuries or bodily deformities or an aggravation of such injuries or deformities, as distinct from other products that cannot prevent specific movements, yet prevent reflex movements (movements carried out subconsciously) through the relative inflexibility of those products due to, for example, flexible splints, pressure pads, non-elastic textile material, restrictions through "Velcro-type" straps.'.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 April 2020.

For the Commission,
On behalf of the President,
Stephen QUEST
Director-General
Directorate-General for Taxation and Customs Union

([3]) Commission Implementing Regulation (EU) 2018/787 of 25 May 2018 concerning the classification of certain goods in the Combined Nomenclature (OJ L 134, 31.5.2018, p. 1).