Executive summary

The Italian Budget Law 2019 (Law no. 145/2018), published in the Official Gazette on 31 December 2018, clarifies that the reduced Value Added Tax (VAT) rate of 10% applicable for medicines also applies to medical devices based on substances generally used for therapeutic or prophylactic purposes and medical and veterinary treatments, classifiable in the tariff code 3004.

Medical devices not falling under the new provision could benefit from the reduced VAT rate should they be included in some other categories of products.

An analysis of the tariff codes of medical devices contained in the product portfolio can ensure the accurate application of the VAT rate and appropriate pricing.

Detailed discussion

Medical devices can be subject to the ordinary VAT rate of 22% or a reduced VAT rate of 10% or 4% respectively - provided that they are reported in one of the tables attached to DPR no. 633/1972.

The tables do not specifically mention medical devices, but rather Tariff codes. Consequently, in order to benefit from the reduced VAT rate, the devices have to be included in one of the categories reported under the appropriate nomenclature code.
VAT reduced rate on medical devices used for therapeutic or prophylactic purposes

Table A part III attached to DPR no. 633/1972, point 114, provides for the application of the reduced VAT rate of 10%, for medicines ready for human and veterinary use, including homeopathic products; pharmaceutical substances and medication items the provision of which is compulsory for pharmacies in accordance with the official pharmacopoeia.

The Budget Law for FY 2019 includes an authentic interpretation of point 114 of table A part III of DPR no. 633/1972, clarifying that medical devices used for therapeutic, prophylactic or preventive purposes and medical and veterinary treatments, classifiable in the code 3004 of the attachment 1, of Commission implementing regulation (EU) 2017/1925 of 12 October 2017, amending Annex 1 to Council Regulation(EEC) no. 2658/1987 on the tariff and statistical nomenclature and on the Common Customs Tariff, must be intended as included in point 114 of the table attached to DPR no. 633/1972 and therefore subject to the reduced 10% VAT rate.

In particular, nomenclature code 3004 includes medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packagings for retail sale.

VAT reduced rate on medical devices not used for therapeutic or prophylactic purposes

Medical devices not falling under mentioned point 114 could however benefit from the reduced VAT rate provided that they are included in one of the other points of the tables attached to DPR no. 633/1972 such as:

- Point 80 table A part III (10%): food preparations (combined nomenclature 21.06) not elsewhere specified or included elsewhere, except syrups.
- Point 30 of table A part II (4%): orthopedic instruments (including medical-surgical belts); devices and equipment for fractures (showers, slats and the like); devices and instruments for dentures, eyes and others; hearing aids and other hand-held equipment to be carried by persons or to be inserted in the entity, to compensate for a deficiency or a disability.
- Point 33 of table A part II (4%): parts, spare parts and accessories intended exclusively for goods referred to in previous numbers 30).
- Point 41-quarter of table A part II (4%): prostheses and aids related to functional permanent disability.

How to determine the correct VAT rate of medical devices

In order to ascertain the correct VAT rate of medical devices, taxpayers can file a request for technical analysis with the Italian Customs Authorities and then a ruling request with the Italian Revenue Agency.
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Indirect Tax

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EYG no. 012875-18Gbl
1508-1600216 NY
ED None

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