

## **EU excludes Chinese companies from major contracts in the medical device sector**

First-ever measure under the IPI instrument and a further step in the EU's tougher stance on China

7 July 2025

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By Implementing Regulation (EU) 2025/1197, published on Friday, 20 June 2025, the European Commission decided to exclude companies from the People's Republic of China (PRC) from public contracts for medical devices. This applies to contracts with an estimated value of more than five million euros. Furthermore, no more than 50% of the contract value may be passed on to Chinese companies.

By excluding Chinese companies, the European Commission is sending another clear signal in the long-simmering conflict with China, in the context of accusations of unfair competition and the refusal to open up the Chinese market. Austrian and EU clients are also directly affected: they must take the 50% limit concerning Chinese companies into account in their tenders and contracts. The successful bidder may face (severe) penalties.

### **Far-reaching exclusion**

The exclusion of companies from the PRC is comprehensive. It covers a wide range of products (identified by CPV codes 33100000-1 to 33199000-1) from simple medical items such as masks, bandages, hygiene products, medical clothing and wheelchairs, to complex devices such as heart valves, lasers, imaging equipment, prostheses, X-ray machines, scanners and MRI systems. According to EU figures, the medical device market in the EU reached a value of EUR 150 billion in 2023, with 50-70% of this accounted for by public tenders. Implementing Regulation (EU) 2025/1197 notes that while contracts over EUR 5 million represented only 4% of all awards, they accounted for 59% of the total contract value.

### **Simmering trade conflict**

The conflict with China over trade in medical devices has been ongoing for months. In January 2025, the European Commission confronted Beijing with the accusation that EU companies face discriminatory treatment when attempting to access the Chinese medical device market. According to the Commission, 87% of tenders in this sector in China disadvantage EU manufacturers through discriminatory requirements. In addition to the dispute over medical devices, the broader trade conflict with China had already intensified as a result of EU measures targeting Chinese electric vehicles.

### **Debut for the IPI**

The exclusion of Chinese companies is the first measure taken by the European Commission under Regulation (EU) 2022/1031 on the access of economic operators, goods and services from third countries to the Union market for public procurement – referred to as the Instrument for Procurement (IPI). The IPI was introduced in response to the EU's recognition that its public procurement market is one of the largest and most open in the world. However,

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many of the EU's trading partners maintain restrictive measures that discriminate against EU companies. The IPI enables the EU to take appropriate countermeasures following upstream investigations and consultations. This is comparable to the UK's exclusion of certain Chinese companies from medical device tenders.

## **Restrictive stance of the European Court of Justice**

In addition to the European Commission, the European Court of Justice (ECJ) has also recently adopted a restrictive approach regarding the access of Chinese companies to the EU procurement market. In decisions C-652/22 (Kolin, 22 October 2024) and C-266/22 (Qingdao, 13 March 2025), the ECJ upheld limitations on their participation. As China is not a member of the international Government Procurement Agreement (GPA), Chinese companies generally have no guaranteed right to participate in EU tenders.

## **Contracting authorities must comply but retain discretion over China**

As a direct consequence of the exclusion of companies from the PRC from EU tenders in the field of medical devices, contracting authorities in Austria and across the EU are obliged to implement the IPI measures. Specifically, this means that they must comply with the obligations arising from the exclusion of Chinese contractors under Art 8 of the IPI Regulation (EU) 2022/1031, by reflecting these requirements in tender documents and contracts. One key requirement is the prohibition on subcontractors supplying goods originating from Chinese companies.

The origin or source of the economic operators and medical devices affected by the exclusion must be determined by the contracting authorities in accordance with the criteria set out in the EU Customs Code. The determination of origin is based, in particular, on Article 60 of Regulation (EU) No. 952/2013 and can, depending on the type of production, raise complex questions of classification.

## **Underlying choice on engagement with China remains with contracting authorities**

Aside from the specific exclusion measures, contracting authorities are still, in principle, free to deny Chinese companies the opportunity to participate in the tenders – for instance, when the aim is to strengthen European value creation. Conversely, contracting authorities may also choose to explicitly allow Chinese companies to participate, particularly where the objective is to promote international competition.

## About Wolf Theiss

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