

Translation / Original: German

Readers are requested to note that this is a translation for information purposes only.

The original German text is legally binding.

## Membership Fee Scale (Beitragsschlüssel) of VDPH

Membership fees are payable on net domestic sales (§ 10 I of the VDPH Statutes) in Germany that are invoiced by or on behalf of the member company. In this context, it is irrelevant whether there are special invoicing modalities inside a business group. Membership fees are payable on sales in Germany that the member company with its distribution arrangements achieves with the below defined products with customers in Germany and invoices to customers in Germany. This also applies if parties who issue invoices or to whom invoices are made out are located outside Germany.

- Membership fees are payable primarily on sales achieved with *in vitro* diagnostic medical devices according to Article 2(2) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices (IVDR) and sales achieved with medical devices according to Article 2(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) to the extent that these generate diagnostic [measured] data.
- Membership fees are payable on sales achieved with laboratory diagnostic services in the meaning of § 2(1) of the VDPH Statutes.
- Membership fees are payable on sales achieved with veterinary diagnostica according to § 2(2) no. 4 of the German Medicinal Products Act (AMG).
- Uniformly for all products and services, the membership fee rate is 0.080 percent for sales amounting up to 50 million €.
- In the membership fee calculation, the membership fee rate is 0.030 percent for sales exceeding 50 million € and 0.020 percent for sales exceeding 500 million €.
- For member companies which do not realize sales with *in vitro* diagnostic medical devices, medical devices or laboratory diagnostic services but with pre-products for these and/or with accessories or laboratory software for use in *in vitro* diagnostic medical devices or tests/devices e.g. for analysis in research or the analysis of foodstuffs, pharmaceuticals, environment and cosmetics (life science research), membership fees are payable on sales achieved with these products in Germany – differentiated by amounts of sales as stated above.
- The minimum membership fee is 5,000.00 €. It is fully taken into account when calculating the membership fees based on sales.

**EXPLANATIONS ON MEMBERSHIP FEE CALCULATION****Sales on which membership fees are payable****1. Sales achieved with diagnostica** comprise:

- Reagents (reagent products), calibrator substances, control materials, kits for the examination of human (Article 2(2) IVDR) and animal specimens.
- Analytical devices including the appertaining software for use in the above reagents (reagent products), and
- spare parts and accessories / consumables as well as service for these, and
- laboratory diagnostic services in the meaning of § 2(1) of the VDGH Statutes.

**2. Sales achieved with medical devices** (Article 2(1) MDR) that generate exclusively diagnostic measured data, e.g. sensor-supported measuring systems for glucose measuring.

**3. If no sales are achieved in the meaning of items 1 and 2** this comprises:

- Reagents (reagent products), calibrator substances, control materials for the examination of foodstuffs, pharmaceutical products, environmental samples, cosmetic products and similar (e.g. research reagents), and
- pre-products for the manufacture of the above reagents (reagent products).
- Devices for use with the above reagents (reagent products), accessories and software – including services, licenses and software maintenance contracts in the meaning of § 1 I sentence 4 of the VDGH Statutes, and
- pre-products for the manufacture of the above analytical devices.

**If the sales of one member company exceed 500 million €, the following sliding scale applies for membership fees:**

Example:	Total sales	600 million € (= 100%)		
	out of this: 50 million € sales	at 0.080 %	=	40,000.00 €
	out of this: 450 million € sales	at 0.030 %	=	135,000.00 €
	out of this: 100 million € sales	at 0.020 %	=	20,000.00 €
				<b>Membership fee 195,000.00 €</b>

Berlin, 17 May 2018