

Name and address of the notified bodies	Identification number	Responsible for the following products	Responsible for the following procedures / modules	Annexes / articles of the directives
RWTÜV e.V. ZERTIFIZIERUNGSSTELLE FÜR GERÄTESICHERHEIT, AUFZÜGE UND MEDIZINTECHNIK Langemarckstrasse, 20 45141 ESSEN Germany	0044	Device for self-testing	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII
		Products referred in Annex II, list B	Full quality assurance system Production quality assurance	Annex IV Annex VII
TÜV PRODUCT SERVICE GMBH Ridlerstraße, 65 80339 MÜNCHEN Germany	0123	Device for self-testing	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII
		Products referred in Annex II, list A	Full quality assurance system EC Type-examination Production quality assurance	Annex IV Annex V Annex VII
		Products referred in Annex II, list B	Full quality assurance system EC Type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII
DEKRA CERTIFICATION SERVICES (DCS) GmbH Handwerkstraße 15 70565 STUTTGART Germany	0124	Device for self-testing	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII
LANDESGEWERBEANSTALT BAYERN PRÜFSTELLE FÜR GERÄTESICHERHEIT (LGA) Tillystraße, 2 90431 Nürnberg Germany	0125	Device for self-testing	EC declaration of conformity	Annex III
		Products referred in Annex II, list B	Full quality assurance system EC Type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII
TÜV RHEINLAND Product Safety GmbH Am Grauen Stein 51105 Köln Germany	0197	Device for self-testing	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII
		Products referred in Annex II, list A	Full quality assurance system EC Type-examination Production quality assurance	Annex IV Annex V Annex VII
		Products referred in Annex II, list B	Full quality assurance system EC Type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII

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TNO CERTIFICATION B.V. Schoemakerstraat 97 - Postbus 6080 2600 JA DELFT Netherlands	0336	In vitro diagnostic medical devices	EC declaration of conformity Full quality assurance system EC Type-examination EC verification Production quality assurance	Annex III Annex IV Annex V Annex VI Annex VII
GROUPEMENT POUR L'ÉVALUATION DES DISPOSITIFS MÉDICAUX 33, avenue du Général Leclerc BP n° 8 92260 FONTENAY-AUX-ROSES France	0459	In vitro diagnostic medical devices	EC declaration of conformity Full quality assurance system EC Type-examination EC verification Production quality assurance	Annex III Annex IV Annex V Annex VI Annex VII
AMTAC CERTIFICATION SERVICES LTD Norman Road - Broadheath WA14 4EP ALTRINCHAM United Kingdom	0473	All devices for self-testing	EC declaration of conformity	Annex III
		All devices referred in Annex II, list A All devices referred in Annex II, list B and all devices for self-testing	Full quality assurance system EC Type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII
MDC MEDICAL DEVICE CERTIFICATION GmbH Krautstraße, 2 87700 MEMMINGEN Germany	0483	Device for self-testing	EC declaration of conformity	Annex III
		Products referred in Annex II, list B	Full quality assurance system Production quality assurance	Annex IV Annex VII
EUROCAT - INSTITUTE FOR CERTIFICATION AND TESTING GMBH Wittichstrasse, 2 64295 DARMSTADT Germany	0535	Device for self-testing Products referred in Annex II, list B	Full quality assurance system Production quality assurance	Annex IV Annex VII
UL INTERNATIONAL (UK) LTD Wonersh House Building C, the Guildway, GU3 1LR Guilford United Kingdom	0843	Reagents and reagent products, including related calibrators and control materials, for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis Reagents and reagent products, including related calibrators and control materials, for determining the following human infections: cytomegalovirus, chlamydia	Full quality assurance system	Annex IV
LABORATÓRIO DE ENSAIOS E METROLOGIA DA SAÚDE - LEMES Av. Padre Cruz, Complexo Inst. Ricardo J 1699 Lisboa Codex Portugal	0932	In vitro diagnostic medical devices	Full quality assurance system EC Type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII