1copy™ Global Compliance and Certifications

CE IVD	**Europe – CE IVD** • Registration # DE/CA70/40838-154617 • Standards Applied: EN ISO 13485:2016, EN 15223-1:2016, EN 13612:2002/AC:2002, EN 13975:2003, EN ISO 14971:2012, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 181132:2011, EN ISO 23640:2015
FDA	**USA** Emergency Use Authorization (EUA) for emergency use of your product,2 pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act. Supply to Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.
KFDA Korea Food & Drug Administration 식품의약품안전청	**South Korea** Free Sales Certification (Korea Food and Drug Administration)
	Canada **Health Canada** Authorization Reference # 312777 Dated 29 March 2020 Device Class/Classe de l'instrument : 3
الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority	**Saudi Arabia** **Saudi Food and Drug Authority** Medical Device National Listing No. ME0000015540SFDAA00001 Dated: 11 April 2020 Authorization Reference # GHTF-2020-0838
Ministry of Health Republic of Poland	**Republic of Poland** Ministry of Health f Article 10 of the IVDD 98/79/EC for