Dear Valued Customer,

Thank you for your inquiry regarding Hologic's readiness to the Regulation 2017/746 on in-vitro diagnostics (IVDR).

An IVDR Programme was initiated in 2018 to ensure compliance of the Hologic IVD products which included the following key workstreams:

- A Quality Systems workstream to review, update and audit our procedures and work instructions,
- A Notified Body workstream, to ensure close communication and a smooth transition through continued support from Notified Bodies,
- A Product Documentation workstream, to review our documents related to product design,
- An Economic Operator workstream, to implement processes regarding the importer, distributor and authorised representative duties,
- A UDI/Eudamed workstream to fulfill the new labelling and registration requirements.

As part of this programme a detailed product analysis was conducted, and Hologic has categorized its portfolio of products against the IVDR classifications (see table below).

Molecular Products	Class A	Class B	Class C	Class D
Assay Reagent Kits	Not applicable	Panther Fusion FluA/B/RSV Assay Panther Fusion Adv/hMPV/RV Assay Panther Fusion Paraflu Assay Panther Fusion Internal Control Aptima BV Assay	Aptima HPV assay Aptima HPV 16 18/45 Genotype Assay Aptima Combo 2 Assay* Aptima CT assay* Aptima GC assay Aptima Trichomonas vaginalis Assay Aptima Mycoplasma genitalium Assay Aptima HSV1&2 Assay Aptima CV/TV Assay Aptima CMV Assay* Panther Fusion GBS assay Panther Fusion MRSA Assay	Aptima HIV Quant DX Assay** Aptima HCV Quant DX Assay** Aptima HBV Quant Assay** Aptima SARS-CoV-2 Assay
Instrumentation	Panther System Panther Plus Panther Fusion System Tomcat Instrument	Not applicable	Not applicable	Not applicable
Specimen Collection and Transfer	Aptima Multitest Swab Collection Kit Aptima Urine Specimen Collection Kit Aptima Unisex Swab Collection Kit Aptima Cervical Specimen Collection and Transport Kit Aptima DBS Extraction Buffer Aptima Specimen Diluent Kit Panther Fusion Lysis Tube Specimen Lysis Tubes	Not applicable	Not applicable	Not applicable
Universal Reagents and consumables	Panther Aptima Assay Fluids Kit Aptima Auto Detect Kit Syscheck	Not applicable	Not applicable	Not applicable

*Current IVDD certification expires May 2023
** Current IVDD certificate expires May 2024

Hologic BV, The Corporate Village, Building Caprese, 3th floor, Da Vincilaan 5, 1930 Zaventem, Belgium
T: +32 2 711 46 80 | F: +32 2 725 20 87 | Hologic.com
BNP PARIBAS FORTIS, IBAN BE75 2100 8769 7651, BIC BEBABEBB, BTW: BE 0445 434 787, RPR Brussel: 0445 434 787

Cytology Products	Class A	Class B	Class C	Class D
Specimen Collection	PreservCyt Solution Vials ThinPrep UroCyte PreservCyt Solution Vial	Not Applicable	Not Applicable	Not Applicable
Gynaecological Cytology	ThinPrep Microscope Slides ThinPrep Imager Microscope Slides ThinPrep Gynecological Filters ThinPrep Nuclear Stain ThinPrep Rinse Solution ThinPrep Bluing Solution ThinPrep Bluing II Solution ThinPrep Orange G Solution ThinPrep EA Solution	Not Applicable	Not Applicable	Not Applicable
General Cytology	CytoLyt Solution ThinPrep Filters for General Cytology (blue) ThinPrep UroCyte Filters (yellow) ThinPrep Microscope slides for General Cytology ThinPrep UroCyte Microscope Slides Cellient Filter cassette Kit CellFyx Solution	Not Applicable	Not Applicable	Not Applicable
Instrumentation	ThinPrep 5000 Processor ThinPrep 5000 Autoloader Processor Compass Stainer Cellient Automated Cell Block System	Not Applicable	Genius Digital Diagnostic System ThinPrep Integrated Imager	Not Applicable

Perinatal Products	Class A	Class B	Class C	Class D
Assay Reagent Kits	Not applicable	Not applicable	Rapid fFN 10Q Cassette Kit	Not applicable
Instrumentation	TLiIQ System	Not applicable	Not applicable	Not applicable
Specimen Collection and Transfer	Rapid fFN Specimen Collection Kit	Not applicable	Not applicable	Not applicable

In conjunction with this analysis, remediation work and engagement with our notified body we expect that the whole Hologic diagnostic portfolio will be compliant with IVDR. Based on our remediation activities we anticipate all claims will remain in place except for Gynecological samples collected in PreservCyt solution for use with the Aptima Mycoplasma genitalium assay.

We are routinely engaging with our notified body and working to an agreed timeline of product submissions and reviews to ensure all products that need to meet IVDR requirements do so by May 2022.

There are several products identified in the table which will still have a valid IVDD certificate until either May 2023 or May 2024. Whilst these products will remain compliant under IVDD certification our plan is to ensure these products are also compliant with IVDR.

Please do not hesitate to contact us should you wish to receive further information.

Geoffray Colson
Head of RAQA, Regulatory and Quality – International
Hologic BV, The Corporate Village, Building Caprese, 3th floor, Da Vincilaan 5, 1930 Zaventem, Belgium
T: +32 2 711 46 80 | F: +32 2 725 20 87 | Hologic.com
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