	Name	Title
Document Author:		
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Intended Use:

The ThinPrep2000 and ThinPrep5000 System is intended as a replacement for the conventional method of Pap smear preparation for use in screening for the presence of atypical cells, cervical cancer, or its precursor lesions (Low-grade Squamous Intraepithelial Lesions, High-grade Squamous Intraepithelial Lesions) as well as all other cytologic categories as defined by The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnosis.

The ThinPrep Solutions are to be used as fluid-based media accessories to the Hologic ThinPrep processors for specimen collection, preparation, and transportation.

Device List:

REF #	Description	GMDN	Date of Conformity
70097-003	PreservCyt Solution Vial* (gynecologic use / non-gynecologic use)	57952	03 NOV 2008
70098-002	PreservCyt Solution vials; gynecologic use, 250 pack	57952	03 NOV 2008
70097-002	PreservCyt Solution Vial** (gynecologic use / non-gynecologic use)	47775	03 NOV 2008
0234005	PreservCyt Solution vials; non-gynecologic use, 50-pack	47775	03 NOV 2008
70787-002	PreservCyt Solution vials; non-gynecologic use, 50-pack	47775	03 NOV 2008
0234004	PreservCyt Solution; non-gynecologic use (bottle/4-pack)	47775	03 NOV 2008
70406-002	PreservCyt Solution; non-gynecologic use (bottle/4-pack)	47775	03 NOV 2008
ASY-05248	PreservCyt Collection Medium, 50 pack	57952	03 NOV 2008
70908-001	ThinPrep UroCyte Collection Kit (20 Pack)	46023	14 DEC 2007
70991-001	ThinPrep UroCyte PreservCyt (50 Pack)	47775	14 DEC 2007
0236004	CytoLyt Solution bottles, 4-pack	57927	03 NOV 2008
70408-002	CytoLyt Solution bottles, 4-pack	57927	03 NOV 2008
0236050	CytoLyt Solution cups, 50-pack	57927	03 NOV 2008
70409-002	CytoLyt Cups (40 Pack Europe)	57927	03 NOV 2008 OBSOLETE

			3 JAN 2017
0236080	**CytoLyt Solution centrifuge tubes, 80-pack**	**57927**	**03 NOV 2008**
70882-001	**CytoLyt Solution (20 Pack)**	**57927**	**03 NOV 2008 OBSOLETE 3 JAN 2017**
70207-001	**CellFyx Solution: 6 pack**	**57743**	**04 NOV 2008**

*Vials are sold in quantities of 250. **Vials are sold in quantities of 50.

Standards to which conformity is declared:

Standard number	Description
EN ISO 14971	**Medical Devices – Application of risk management to medical devices**
EN ISO 13485	**Medical Devices – Quality management systems-requirements for regulatory purposes**
EN 13612	**Performance evaluation of IVD medical devices**
EN ISO 15223-1	**Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.**
EN ISO 18113-1	**In vitro diagnostic medical devices – Information supplied by the manufacturer(labeling) Part 1: Terms, definitions and general requirements**
EN ISO 18113-2	**In vitro diagnostic medical devices – Information supplied by the manufacturer(labeling) Part 2: In vitro diagnostic reagents for professional use**
EN ISO 23640	**In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents**
49CFR Section 178.608	**Vibration Standard**
EN 980	**Symbols for use in the labeling of medical devices**

Quality System Registration: **ISO 13485:2003**

Applicable Directive:

☒ IVD Directive 98/79/EC ☐ Medical Device Directive 93/42/EEC

Classification/Rule: Non Annex II Listed

Conformity Assessment Route: Annex III

Notified Body (if applicable): Not Applicable

We hereby declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC including applicable essential requirements of Annex I for legal application of the CE Mark. All supporting documentation is retained on the premises of the manufacturer.