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EC DECLARATION OF CONFORMITY TO MEDICAL DEVICES DIRECTIVE 93/42/EEC amended by DIRECTIVE 2007/47/EC

MANUFACTURER: PROTEK Medical Products, Inc.
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MEDICAL DEVICES:
Sterile single-use probe and instrument covers for surgical procedures,
Sterile single-use endocavity probe covers,
Sterile single-use system drapes,
Sterile single-use general purpose and endocavity needle guides, and
Ultrasound & imaging procedures kits incorporating the above devices and conductive gel.

EC PRODUCT CLASSIFICATION:

Class IIa	
<ul style="list-style-type: none"> • Sterile Single-use General Purpose and Instrument covers for surgical procedures • Sterile single use ultrasound & imaging procedure kits 	Rule 6: surgically invasive, transient use.
Class Is	
<ul style="list-style-type: none"> • Sterile Single-use Endocavity Probe covers 	Rule 5: all invasive, with respect to body orifices, transient use.
<ul style="list-style-type: none"> • Sterile single use system drapes 	Rule 1: non-invasive, no patient contact.
<ul style="list-style-type: none"> • Sterile single use general purpose needle guides 	Rule 1: non-invasive, contact with intact skin, OR no contact.
<ul style="list-style-type: none"> • Sterile single use endocavity needle guides 	Rule 5: all invasive, with respect to body orifices, transient use.

European Representative: EMERGO EUROPE BV
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We hereby declare that the above mentioned medical devices comply with the essential requirements and provisions of Annex II, section 3.2 of the Council Directive 93/42/EEC as amended by directive 2007/47/EC, under supervision of **NL BSI**, Notified Body Number **2797**.

Rick L. Pruter
President/CEO
Protek Medical Products, Inc.

5-14-19

Date

Needle Guide Product List - Annex B
(Needle Guide Annex to the EC Declaration of Conformity)

Ref	Description
Sterile Disposable Needle Guides	
4013	13 GA Director™ NG
4014	14 GA Director™ NG
4015	15 GA Director™ NG
4016	16 GA Director™ NG
4017	17 GA Director™ NG
4018	18 GA Director™ NG
4019	19 GA Director™ NG
4020	20 GA Director™ NG
4021	21 GA Director™ NG
4022	22 GA Director™ NG
4023	23 GA Director™ NG
4025	25 GA Director™ NG
4216	16 GA Director™ NG kit
4216(G)	16 GA Director™ NG kit (no gel)
4218	18 GA Director™ NG kit
4218(G)	18 GA Director™ NG kit (no gel)
4220	20 GA Director™ NG kit
4220(G)	20 GA Director™ NG kit (no gel)
4221(G)	21 GA Director™ NG kit (no gel)
4222	22 GA Director™ NG kit
4222(G)	22 GA Director™ NG kit (no gel)
4500	Director XT™ NG
4501	Director XT™ NG kit
4741	Rivanna™ NG kit
4742	Rivanna™ NG
5014	GE BE9C Endo NG kit (no gel)
5017	GE BE9C Endo NG kit
5025	Lorad, 14 GA, Closed NG
5026	Lorad, 16-19 GA, Closed NG
5027	Lorad, 20-22 GA, Closed NG
5028	Lorad, 16-19 GA, Open NG
5029	Lorad, 20-22 GA, Open NG
5045	Shimadzu TV11R-055U Endo NG
5046	GE 618E Endo NG
5049	Shimadzu EC11R-055U Endo NG
5055	GE E8C/E721 1 PC. Endo NG
5056	GE E8C/E721 1PC. Endo NG kit (Itx)
5058	GE E8C/E721 1PC. Endo NG kit
5059	GE E8C/E721 1PC. Endo NG kit
5070	GE RIC5-9H Endo NG

Ref	Description
Non-Sterile Reusable Needle Guides	
6005	Shimadzu TV11R, Endo NG, 16 Ga
6006	Shimadzu TV11R, Endo NG, 14 Ga
6026	GE BE9C, Endo NG, 16 Ga
6042	Medison EC4-9IS, Endo NG, 16 Ga
6043	Medison EC4-9-10ED, Endo NG, 16 Ga
6076	GE TR7/618E, Endo NG, 14 Ga
6077	GE TR7/618E, Endo NG, 16 Ga
6080	GE 3CRF V NAV, Sensor bracket
6095	GE E8C/E721, Endo NG, 16 Ga
6097	GE RIC5-9, Endo NG, 16 Ga
6098	GE IC9-RS, Endo NG, 16 Ga
6099	GE 3CRF V NAV, Sensor bracket-Style 2
6116	GE BE9C, Endo NG, 14 Ga
6131	Samsung ER4-9, Endo NG, 16 Ga
6174	Alpinion VE3-10H, Endo NG, 16 Ga
6194	Zonare E9.4, Endo NG, 14 Ga
6252	SSI SE12-3 Endo sensor bracket
6253	SSI SEV12-3 Endo sensor bracket
6254	SSI XC6-1 GP sensor bracket
6255	SSI SL10-2 GP sensor bracket
6256	SSI SE12-3 Endo NG, 16 Ga
6261	Sonoscanner U-Lite bracket
6267	Samsung EV2-10A, Endo NG, 18 Ga
6268	Samsung EA2-11AR, Endo NG, 18 Ga
6340	GE E8C/E721, Endo NG, 14 Ga
6341	B&K 8667, Endo NG, 14 Ga
6370	Hitachi C41V1 Endo NG, 16 Ga
6381	Hitachi EUP-V33 Endo NG, 14 Ga
6382	Hitachi EUP-V33 Endo NG, 16 Ga
6383	Hitachi EUP-V33 Endo NG, 14 Ga
6384	Hitachi EUP-V33 Endo NG, 16 Ga
6390	Esaote EC123 Endo NG, 16 Ga
6391	ATL/Philips C9-5, Endo NG, 14 Ga
6392	ATL/Philips C9-5, Endo NG, 16 Ga
6415	Sonosite HFL38 GP SA Bracket
6449	GE E8C/E721 Endo NG, 16 Ga
6455	Medison ER(V)4-9/10ED Endo NG, 16 Ga
6456	Ultrasonix EC9-5/10EZ Endo NG, 16 Ga
6465	Shimadzu UB10R-065U Endo NG, 14 Ga
6466	Shimadzu UB10R-065U Endo NG, 16 Ga

Needle Guide Product List - Annex B
(Needle Guide Annex to the EC Declaration of Conformity)

Ref	Description
Sterile Disposable Needle Guides (Cont.)	
5071	GE RIC5-9H Endo NG kit (ltx)
5072	GE RIC5-9H Endo NG kit (non-ltx)
5074	GE RIC5-9H Endo NG kit (ltx/non-ltx)
5142	Alpinion VE3-10H Endo NG
5144	Medison EV4-9/10ED Endo NG
5145	Esaote EC123 Endo NG
5146	Medison EV4-9/10ED Endo NG kit (ltx)
5147	Esaote EC123 Endo NG kit (ltx)
5148	Esaote EC123 Endo NG kit
5149	Medison EV4-9/10ED Endo NG kit
5151	Esaote EC123 Endo NG kit
5154	Samsung 3D4-9 Endo NG
5156	Samsung 3D4-9 Endo NG kit (ltx)
5157	Samsung 3D4-9 Endo NG kit
5159	Samsung EV4-9/10ED Endo NG kit
5171	Sonoscape 6V4 Endo NGs
5172	Sonoscape 6V1 Endo NGs
5174	Mindray& other Probes Endo NG
5175	Sonoscape 6V4 Endo NG kit (ltx)
5176	Sonoscape 6V4 Endo NG kit
5178	Sonoscape 6V1 Endo NG kit (ltx)
5179	Sonoscape 6V1 Endo NG kit
5183	Samsung EV4-9/10ED Endo NG kit
5250	Samsung NEV4-9ES Endo NG
5252	Samsung NEV4-9ES Endo NG kit (ltx)
5253	Samsung NEV4-9ES Endo NG kit
5260	Samsung E3-12A Endo NG
5261	Samsung E3-12A Endo NG kit
5262	Samsung E3-12A Endo NG kit (ltx)
5263	Samsung E3-12A Endo NG kit
5270	Philips C8-4v Endo NG
5271	Philips C8-4v Endo NG kit
5272	Philips C8-4v Endo NG kit (ltx)
5273	Philips C8-4v Endo NG kit
5275	Samsung EV2-10A Endo NG
5280	Eigen NG kit
5281	Eigen NG
5285	Philips C9-4v Endo NG
5295	Samsung EA2-11B Endo NG
5313	13 GA Retrofit™ NG

Ref	Description
Non-Sterile Reusable Needle Guides (Cont.)	
6467	Shimadzu EC11R-055U Endo NG, 16 Ga
6476	Acuson/Siemens EC7 Endo NG, 14 Ga
6477	Siemens EC9-4, Endo NG, 14 Ga
6478	Siemens P2, Endo NG, 14 Ga
6482	Siemens P2, Endo NG, 16 Ga
6487	Medison C2-8 GP SA Bracket
6531	Toshiba PVM-651VT, Endo NG, 14 Ga
6532	Toshiba PVG-600S, Endo NG, 14 Ga

Biopsy Procedure Starter Kits	
7024	Zonare C5-2 SA GP
7026	GE BE9C Endo
7050	GE E8C/E721 Endo
7060	GE 3.5C/3.5CS/348C SA GP
7061	GE M12L, MA GP
7063	GE 10L/739L MA GP
7064	GE M7C MA GP
7068	GE 9L MA GP
7069	GE 7L/546L SA GP
7070	GE 4C MA GP
7074	GE 12L/LA39 SA GP
7075	GE 12L/LA39 MA GP
7082	GE 3CRF Multi gauge NG
7083	GE 3CRF 13-15 GA Replacement Kit
7086	GE 3CRF 16-19 GA Replacement Kit
7090	GE 3CRF 20-23 GA Replacement Kit
7132	Medison 3DC2-6 GP
7137	Terason 15L4/Vermon L7 SA GP
7138	Terason 4C2-V GP
7142	Medison EC4-9IS/EC4-ES Endo
7143	Medison EC4-9-10ED Endo
7145	Medison L5-12/50EP GP
7147	Medison HL5-12ED GP
7148	Medison C2-5EP GP
7149	Medison L5-12/40EP GP
7152	Medison C3-7EP GP
7154	Medison C2-5 GP, Plastic
7156	Medison C2-5 GP, SS
7157	Ultrasonix L14-5/38 GP

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Ref	Description
Sterile Disposable Needle Guides (Cont.)	
5314	14 GA Retrofit™ NG
5315	15 GA Retrofit™ NG
5316	16 GA Retrofit™ NG
5317	17 GA Retrofit™ NG
5318	18 GA Retrofit™ NG
5319	19 GA Retrofit™ NG
5320	20 GA Retrofit™ NG
5321	21 GA Retrofit™ NG
5322	22 GA Retrofit™ NG
5323	23 GA Retrofit™ NG
5325	25 GA Retrofit™ NG
5370	Hitachi C41V1 Endo NG
5371	Hitachi C41V1 Endo NG kit
5372	Hitachi C41V1 Endo NG kit (ltx)
5373	Hitachi C41V1 Endo NG kit
5380	Hitachi EUP-V33 Endo NG
5381	Hitachi EUP-V33 Endo NG kit
5382	Hitachi EUP-V33 Endo NG kit (ltx)
5383	Hitachi EUP-V33 Endo NG kit
5395	Philips C9-4v Endo NG
5401	3.5cm Pro-V Access™ NG
5402	1.5cm Pro-V Access™ NG
5403	1.0cm Pro-V Access™ NG
5404	0.5cm Pro-V Access™ NG
5405	2.0cm Pro-V Access™ NG
5406	2.5cm Pro-V Access™ NG
5410	3 depths Pro-V Access™ NG kit
5414	3 depths Pro-V Access™ NG kit
5415	3 depths Pro-V Access™ NG kit
5416	3 depths Pro-V Access™ NG kit
5417	3 depths Pro-V Access™ NG kit
5430	3 depths Pro-V Access™ NGs
5431	3 depths Pro-V Access™ NGs
5432	3 depths Pro-V Access™ NGs
5444	4 depths Pro-V Access™ NG kit
5445	4 depths Pro-V Access™ NGs
5480	Siemens EC9-4 Endo NG
5513	13 GA Retrofit™ NG and drape kit
5514	14 GA Retrofit™ NG and drape kit
5515	15 GA Retrofit™ NG and drape kit
5516	16 GA Retrofit™ NG and drape kit
5517	17 GA Retrofit™ NG and drape kit

Ref	Description
Biopsy Procedure Starter Kits (Cont.)	
7158	Medison L5-12/50 MA GP
7162	Samsung L3-12A MA GP
7162(G)	Samsung L3-12A MA GP (No Gel)
7164	Samsung SC1-6 MA GP
7165	Samsung LF5-13/LA3-16A MA GP
7165(G)	Samsung LA3-16A MA GP (No Gel)
7166	Samsung CF2-8 MA GP
7166(G)	Samsung CF2-8 MA GP (No Gel)
7167	Samsung CA1-7A/ CA1-7AD MA GP
7167(G)	Samsung CA1-7A MA GP (No Gel)
7168	Samsung CV1-8A/ CV1-8AD MA GP
7168(G)	Samsung CV1-8A MA GP (No Gel)
7172	Samsung LF5-13/LA3-16AD MA GP
7172(G)	Samsung LA3-16AD MA GP (No Gel)
7173	Samsung C2-6IC GP
7179	Samsung CF2-8 MA GP
7180	Samsung CA1-7A/CA1-7AD MA GP
7181	Samsung LA2-9A MA GP
7185	Alpinion L3-12X MA GP
7186	Alpinion SC1-4HS MA GP
7187	Alpinion VE3-10H Endo
7190	Samsung 3D5-8EK, Endo
7250	Samsung VN4-8 MA GP
7250(G)	Samsung VN4-8 MA GP (No Gel)
7257	Ultrasonix L14-5/38 GP
7265	Samsung CF4-9 MA GP
7285	Samsung LA4-18A MA GP
7308	GE C1-5 MA GP
7309	GE C1-6 MA GP
7350	Esaote LA424/435 SA GP
7351	Esaote LA522/523/532 SA GP
7352	Esaote CA421/430/431 Two Angle GP
7354	Esaote CA621/631 Two Angle GP
7356	Esaote CA123 SA GP
7357	Esaote LA522/523/532 Three Angle GP
7360	Esaote EC1123, 16 GA Endo
7384	Hitachi EUP-V53W Short 16 GA Endo
7385	Philips C5-2 GP
7389	Philips C9-4EC Endo
7394	Philips C7-3 GP
7411	Zonare E9-4 Endo
7430	GE 6.5C-RC MA GP

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Ref	Description
Sterile Disposable Needle Guides (Cont.)	
5518	18 GA Retrofit™ NG and drape kit
5519	19 GA Retrofit™ NG and drape kit
5520	20 GA Retrofit™ NG and drape kit
5521	21 GA Retrofit™ NG and drape kit
5522	22 GA Retrofit™ NG and drape kit
5523	23 GA Retrofit™ NG and drape kit
5531	Toshiba PVM-651VT Endo NG
5532	Toshiba PVM-651VT Endo NG kit (ltx)
5533	Toshiba PVM-651VT Endo NG kit
5550	Toshiba PVT-781VT Endo NG
5552	Toshiba PVT-781VT Endo NG kit (ltx)
5560	Toshiba PVT-781VT 1° Endo NG
5561	Toshiba PVT-781VT 1° Endo NG kit
5562	Toshiba PVT-781VT Endo NG kit (ltx)
5563	Toshiba PVT-781VT 1° Endo NG kit
5570	GE IC9-RS Endo NG
5575	Sonosite ICTx/8-5 Endo NG
5585	Chison D6C12L Endo NG
5595	Chison D7C10L Endo NG
5600	Retrofit XT™ NG
5601	Retrofit XT™ NG kit
5650	Sonoscape EC9-5 Endo NG
5651	Sonoscape EC9-5 Endo NG kit
5652	Sonoscape EC9-5 Endo NG kit (ltx)
5653	Sonoscape EC9-5 Endo NG kit
5655	Sonoscape EC2 Endo NG
7213	13 GA Director™ NG and drape kit
7214	14 GA Director™ NG and drape kit
7215	15 GA Director™ NG and drape kit
7216	16 GA Director™ NG and drape kit
7217	17 GA Director™ NG and drape kit
7218	18 GA Director™ NG and drape kit
7219	19 GA Director™ NG and drape kit
7220	20 GA Director™ NG and drape kit
7221	21 GA Director™ NG and drape kit
7222	22 GA Director™ NG and drape kit
7223	23 GA Director™ NG and drape kit
9000	Mindray 6CV10 and others Endo NG
9001	Mindray 6CV10 Endo NG kit (ltx)
9002	Mindray 6CV10 Endo NG kit
9003	Mindray 6CV10 Endo NG kit (ltx)
9005	Mindray 6CV10 Endo NG kit

Ref	Description
Biopsy Procedure Starter Kits (Cont.)	
7431	GE 4C/3.8C-RC MA GP
7432	GE 7.5L/7L-RC MA GP
7433	GE E7C-RC Endo
7454	Samsung EV4-9/10ED Endo
7455	Prosonic EC10R Endo
7457	Samsung C2-8 GP
7458	Samsung L3-8, LN5-12/40
7459	Samsung L5-12/60 GP
7460	Samsung CN2-8 GP
7461	Samsung LN5-12 GP
7461(G)	Samsung LN5-12 GP (No Gel)
7462	Prosonic C1-5/60 GP
7480	Acuson 4V1 GP
7540	Ultrasonix C5-2/60-1 & C7-3/50-1 GP
7542	Ultrasonix L14-5/38 & L9-4/38 GP
7543	Ultrasonix L14-5W/60 GP
7544	Ultrasonix EC9-5/10 Endo
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Updated 07/11/2019