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Manufacturers Name: PST – Plastic Sterilizing Tray Corporation
Manufacturers Address: 1520 East Street
Pittsfield, MA 01201
USA
SRN (Single Registration Number): FR-AR-000000182
Authorized Representative Name (if applicable): MediMark Europe
Authorized Representative Address (if applicable): 11 rue Emile Zola, BP 2332
F-38033, Grenoble Cedex 2, France
Basic UDI-DI: 81005183
Name of the Device (s): *PLASTIC INSTRUMENT TRAYS AND ACCESSORIES*
Product code: *SEE ATTACHMENT*
Classification: Class I
Conformity assessment route: PST uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745:

Annexes II and III

Class I: EC conformity declaration according to Annex IV

This declaration of conformity is issued under the sole responsibility of Plastic Sterilizing Tray Corporation.
We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for Class I medical devices.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

Place and date (dd.mm.yyyy) of issue:


.....
KELLIE HAZELTON
MANAGEMENT REPRESENTATIVE

05-26-2021
.....

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Attachment to declaration of conformity

LIST OF SALEABLE CATALOG NUMBERS IN SCOPE

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Item-#	Description	DIMENSION IN INCHES	SKU	GTIN	Packaging Level
1023M	SILICONE MAT (NON PERFORATED)	10.0 X 23.0 MAT LIGHT BLUE	1023M	810051831580	Each
1024M	SILICONE MAT (PERFORATED)	10.0 X 23.0 MAT LIGHT BLUE	1024M	810051831573	Each
1080DBM	SILICONE MAT (PERFORATED)	10.32 X 18.22 MAT DARK BLUE	1080DBM	810051831559	Each
1081DBM	SILICONE MAT (NON-PERFORATED)	10.32 X 18.22 MAT DARK BLUE	1081DBM	810051831566	Each
1300A	BASE, LID & MAT	1.5 X 2.7 X 0.75	1300A	810051830002	Each
1300B	BASE ONLY	1.5 X 2.7 X 0.75	1300B	810051830019	Each
1300L	LID ONLY	1.5 X 2.7 LID	1300L	810051830026	Each
1300M	SILICONE MAT ONLY	1.5 X 2.7 MAT	1300M	810051830033	Each
1301A	BASE & LID	1.5 X 2.7 X 0.75	1301A	810051830040	Each
1310A	DEEP BASE, LID & MAT	1.5 X 2.7 X 1.0	1310A	810051830057	Each
1310B	DEEP BASE ONLY	1.5 X 2.7 X 1.0	1310B	810051830064	Each
1311A	DEEP BASE & LID	1.5 X 2.7 X 1.0	1311A	810051830071	Each
1320A	DEEP BASE, LID & MAT	1.5 X 2.7 X 1.25	1320A	810051830088	Each
1320B	DEEP BASE ONLY	1.5 X 2.7 X 1.25	1320B	810051830095	Each
1321A	DEEP BASE & LID	1.5 X 2.7 X 1.25	1321A	810051830101	Each
1380M	SILICONE MAT (PERFORATED)	13.0 X 18.0 MAT LIGHT BLUE	1380M	810051831207	Each
1381M	SILICONE MAT (NON PERFORATED)	13.0 X 18.0 MAT LIGHT BLUE	1381M	810051831191	Each

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Item-#	Description	DIMENSION IN INCHES	SKU	GTIN	Packaging Level
1500A	BASE, LID & MAT	10.0 X 15.0 X 0.75	1500A	810051830781	Each
1500B	BASE ONLY	10.0 X 15.0 X 0.75	1500B	810051830798	Each
1500L	LID ONLY	10.0 X 15.0 X 0.75	1500L	810051830804	Each
1500M	BASE SILICONE MAT ONLY	10.0 X 15.0 x 0.75	1500M	810051830811	Each
1501A	BASE & LID	10.0 X 15.0 X 0.75	1501A	810051830828	Each
1520A	DEEP BASE, LID, INSERT TRAY & 2 MATS	10.0 X 15.0 X 1.5	1520A	810051830835	Each
1520B	DEEP BASE ONLY	10.0 X 15.0 X 1.5	1520B	810051830842	Each
1520I	INSERT TRAY ONLY	10.0 X 15.0 INSERT TRAY	1520I	810051830859	Each
1520M	INSERT SILICONE MAT ONLY	10.0 X 15.0 INSERT MAT	1520M	810051830866	Each
1521A	DEEP BASE & LID	10.0 X 15.0 X 1.5	1521A	810051830873	Each
1522A	DEEP BASE, LID & MAT	10.0 X 15.0 X 1.5	1522A	810051830880	Each
1523A	DEEP BASE, LID, INSERT TRAY & BASE MAT	10.0 X 15.0 X 1.5	1523A	810051830897	Each
1524A	DEEP BASE, LID, INSERT TRAY & INSERT MAT	10.0 X 15.0 X 1.5	1524A	810051830903	Each
2311S	BAR, SILICONE, 1 SLOT OPEN END	PHACO-16MM SILICONE BAR	2311S	810051831238	Each
2312S	BAR, SILICONE, 1 SLOT OPEN END	PHACO-7MM SILICONE BAR	2312S	810051831245	Each
2313S	BAR, SILICONE, 3 SLOT OPEN END	PHACO-7MM SILICONE BAR	2313S	810051831252	Each

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Item-#	Description	DIMENSION IN INCHES	SKU	GTIN	Packaging Level
2314S	BAR, SILICONE, 3 SLOT OPEN END	PHACO-16MM,7MM&13MM SILICONE BAR	2314S	810051831269	Each
2341A	DEEP BASE, LID & (1) 2311S & (1) 2312S	4.0 X 7.5 X 1.5	2341A	810051830446	Each
2343A	DEEP BASE, LID & (1) 2313S & (1) 2314S	4.0 X 7.5 X 1.5	2343A	810051830453	Each
2361A	DEEP BASE, LID & (1) 2311S & (1) 2312S	6.0 X 10.0 X 1.5	2361A	810051830637	Each
2363A	DEEP BASE, LID & (1) 2313S & (1) 2314S	6.0 X 10.0 X 1.5	2363A	810051830644	Each
2501A	BASE, LID & (2) 2511S	2.5 X 6.0 X 0.75	2501A	810051830194	Each
2502A	BASE, LID & (2) 2512S	2.5 X 6.0 X 0.75	2502A	810051830200	Each
2503A	BASE, LID & (2) 2513S	2.5 X 6.0 X 0.75	2503A	810051830217	Each
2503S	BAR, SILICONE, 3 SLOT OPEN END	ROUND-3MM SILICONE BAR	2503S	810051831276	Each
2505A	BASE, LID & (2) 4615S	4.0 X 6.5 X 0.75	2505A	810051830354	Each
2511S	BAR, SILICONE, 1 SLOT OPEN END	ROUND-6MM SILICONE BAR	2511S	810051831283	Each
2512S	BAR, SILICONE, 2 SLOT OPEN END	ROUND-6MM SILICONE BAR	2512S	810051831290	Each
2513S	BAR, SILICONE, 3 SLOT OPEN END	ROUND-6MM SILICONE BAR	2513S	810051831306	Each
2514S	BAR, SILICONE	SMALL FLAT BAR	2514S	810051831313	Each

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Item-#	Description	DIMENSION IN INCHES	SKU	GTIN	Packaging Level
2517S	BAR, SILICONE 7mm	SPECIAL CUT BAR	2517S	810051831320	Each
2519S	BAR, SILICONE ONE SLOT	OPEN END ROUND, 9MM BAR	2519S	810051831337	Each
2523S	BAR, SILICONE, 3 SLOT	STRAIGHT CUT SILICONE BAR	2523S	810051831344	Each
2526S	BAR, SILICONE, 6 SLOT	STRAIGHT CUT SILICONE BAR	2526S	810051831351	Each
2571A	BASE, LID & (2) 2511S	2.5 X 7.5 X 0.75	2571A	810051830279	Each
2572A	BASE, LID & (2) 2512S	2.5 X 7.5 X 0.75	2572A	810051830286	Each
2573A	BASE, LID & (2) 2513S	2.5 X 7.5 X 0.75	2573A	810051830293	Each
2600A	BASE, LID & MAT	2.5 X 6.0 X 0.75	2600A	810051830118	Each
2600B	BASE ONLY	2.5 X 6.0 X 0.75	2600B	810051830125	Each
2600L	LID ONLY	2.5 X 6.0 LID	2600L	810051830132	Each
2600M	SILICONE MAT ONLY	2.5 X 6.0 MAT	2600M	810051830149	Each
2601A	BASE & LID	2.5 X 6.0 X 0.75	2601A	810051830156	Each
2610A	DEEP BASE, LID & MAT	2.5 X 6.0 X 1.25	2610A	810051830163	Each
2610B	DEEP BASE ONLY	2.5 X 6.0 X 1.25	2610B	810051830170	Each
2611A	DEEP BASE & LID	2.5 X 6.0 X 1.25	2611A	810051830187	Each
2700A	BASE, LID & MAT	2.5 X 7.5 X 0.75	2700A	810051830224	Each
2700B	BASE ONLY	2.5 X 7.5 X 0.75	2700B	810051830231	Each
2700L	LID ONLY	2.5 X 7.5 LID	2700L	810051830248	Each
2700M	SILICONE MAT ONLY	2.5 X 7.5 MAT	2700M	810051830255	Each
2701A	BASE & LID	2.5 X 7.5 X 0.75	2701A	810051830262	Each
3361A	DEEP BASE, DOME LID & (1) 2311S & (1) 2312S	6.0 X 10.0 X 2.0	3361A	810051830712	Each

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Item-#	Description	DIMENSION IN INCHES	SKU	GTIN	Packaging Level
3363A	DEEP BASE, DOME LID & (1) 2313S & (1) 2314S	6.0 X 10.0 X 2.0	3363A	810051830729	Each
4600A	BASE, LID & MAT	4.0 X 6.5 X 0.75	4600A	810051830309	Each
4600B	BASE ONLY	4.0 X 6.5 X 0.75	4600B	810051830316	Each
4600L	LID ONLY	4.0 X 6.5 LID	4600L	810051830323	Each
4600M	SILICONE MAT ONLY	4.0 X 6.5 MAT	4600M	810051830330	Each
4601A	BASE & LID	4.0 X 6.5 X 0.75	4601A	810051830347	Each
4612S	BAR, SILICONE, 2 SLOT OPEN END	ROUND-6MM SILICONE BAR	4612S	810051831368	Each
4613S	BAR, SILICONE, 3 SLOT OPEN END	ROUND-6MM SILICONE BAR	4613S	810051831375	Each
4614S	BAR, SILICONE, 4 SLOT OPEN END	ROUND-6MM SILICONE BAR	4614S	810051831382	Each
4615S	BAR, SILICONE, 5 SLOT OPEN END	ROUND-6MM SILICONE BAR	4615S	810051831399	Each
4666S	BAR, SILICONE, 6 SLOT	STRAIGHT CUT SILICONE BAR	4666S	810051831405	Each
4669S	BAR, SILICONE, 12 SLOT	STRAIGHT CUT SILICONE BAR	4669S	810051831412	Each
4700A	BASE, LID & MAT	4.0 X 7.5 X 0.75	4700A	810051830361	Each
4700B	BASE ONLY	4.0 X 7.5 X 0.75	4700B	810051830378	Each
4700L	LID ONLY	4.0 X 7.5 LID	4700L	810051830385	Each
4700M	SILICONE MAT ONLY	4.0 X 7.5 MAT	4700M	810051830392	Each
4701A	BASE & LID	4.0 X 7.5 X 0.75	4701A	810051830408	Each
4710A	DEEP BASE, LID & MAT	4.0 X 7.5 X 1.5	4710A	810051830415	Each

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Item-#	Description	DIMENSION IN INCHES	SKU	GTIN	Packaging Level
4710B	DEEP BASE ONLY	4.0 X 7.5 X 1.5	4710B	810051830422	Each
4711A	DEEP BASE & LID	4.0 X 7.5 X 1.5	4711A	810051830439	Each
6100A	BASE, LID & MAT	6.0 X 10.0 X 0.75	6100A	810051830460	Each
6100B	BASE ONLY	6.0 X 10.0 X 0.75	6100B	810051830477	Each
6100L	LID ONLY	6.0 X 10.0 LID	6100L	810051830484	Each
6100M	BASE SILICONE MAT ONLY	6.0 X 10.0 BASE MAT	6100M	810051830491	Each
6101A	BASE & LID	6.0 X 10.0 X 0.75	6101A	810051830507	Each
6103A	BASE, DOME LID & BASE MAT	6.0 X 10.0 X 1.25	6103A	810051830521	Each
6104A	BASE & DOME LID	6.0 X 10.0 X 1.25	6104A	810051830538	Each
6120A	BASE, INSERT TRAY, LID & 2 MATS	6.0 X 10.0 X 1.5	6120A	810051830545	Each
6120B	DEEP BASE ONLY	6.0 X 10.0 X 1.5	6120B	810051830552	Each
6120I	INSERT TRAY ONLY	6.0 X 10.0 INSERT TRAY	6120I	810051830569	Each
6120M	INSERT SILICONE MAT ONLY	6.0 X 10.0 INSERT TRAY MAT	6120M	810051830576	Each
6121A	DEEP BASE & LID	6.0 X 10.0 X 1.5	6121A	810051830583	Each
6122A	DEEP BASE, LID, INSERT TRAY & BASE MAT	6.0 X 10.0 X 1.5	6122A	810051830590	Each
6123A	DEEP BASE, LID, INSERT TRAY & INSERT MAT	6.0 X 10.0 X 1.5	6123A	810051830606	Each
6124A	DEEP BASE, LID & BASE MAT	6.0 X 10.0 X 1.5	6124A	810051830613	Each

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Item-#	Description	DIMENSION IN INCHES	SKU	GTIN	Packaging Level
6125A	DEEP BASE, LID & INSERT TRAY	6.0 X 10.0 X 1.5	6125A	810051830620	Each
6130A	DEEP BASE, DOME LID, INSERT TRAY & 2 MATS	6.0 X 10.0 X 2.0	6130A	810051830651	Each
6130L	DOME LID ONLY	6.0 X 10.0 X 0.50	6130L	810051830514	Each
6131A	DEEP BASE & DOME LID	6.0 X 10.0 X 2.0	6131A	810051830668	Each
6132A	DEEP BASE, DOME LID, INSERT TRAY & BASE MAT	6.0 X 10.0 X 2.0	6132A	810051830675	Each
6133A	DEEP BASE, DOME LID, INSERT TRAY & INSERT MAT	6.0 X 10.0 X 2.0	6133A	810051830682	Each
6134A	DEEP BASE, DOME LID, & BASE MAT	6.0 X 10.0 X 2.0	6134A	810051830699	Each
6135A	DEEP BASE, DOME LID & INSERT TRAY	6.0 X 10.0 X 2.0	6135A	810051830705	Each
6140A	DEEP BASE, LID & MAT	6.0 X 10.0 X 2.5	6140A	810051830736	Each
6140B	DEEP BASE ONLY	6.0 X 10.0 X 2.5	6140B	810051830750	Each
6141A	DEEP BASE & LID	6.0 X 10.0 X 2.5	6141A	810051830743	Each
6150A	DEEP BASE, DOME LID & MAT	6.0 X 10.0 X 3.0	6150A	810051830767	Each
6151A	DEEP BASE & DOME LID	6.0 X 10.0 X 3.0	6151A	810051830774	Each
6500A	BASE, LID & (2) 6520S	2.6 X 12.0 X 1.5	6500A	810051830958	Each
6500B	BASE ONLY	2.6 X 12.0 X 1.5	6500B	810051831528	Each

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6500L	LID ONLY	2.6 X 12.0 X 1.5	6500L	810051830934	Each
6500M	SILICONE MAT ONLY	2.6 X 12.0 MAT	6500M	810051830941	Each
6500S	BAR, SILICONE, BLANK	BLANK SILICONE BAR	6500S	810051831429	Each
6501A	BASE & LID	2.6 X 12.0 x 1.5	6501A	810051830927	Each
6501S	BAR, SILICONE, 2 SLOT OPEN END	10MM & 13MM SILICONE BAR	6501S	810051831436	Each
6502A	SCOPE TRAY, BASE, LID & MAT	2.6 X 12.0 X 1.5	6502A	810051830910	Each
6502S	BAR, SILICONE, 2 SLOT OPEN END	ROUND-10MM SILICONE BAR	6502S	810051831443	Each
6508S	BAR, SILICONE, 1 SLOT	CLOSED END-7MM SILICONE BAR	6508S	810051831450	Each
6509S	BAR, SILICONE, 1 SLOT	CLOSED END-13MM SILICONE BAR	6509S	810051831467	Each
6510A	BASE, LID & (2) 6501S & (1) 6502S	2.6 X 16.0 X 1.5	6510A	810051831016	Each
6510B	BASE ONLY	2.6 X 16.0 X 1.5	6510B	810051830989	Each
6510L	LID ONLY	2.6 X 16.0 LID	6510L	810051830996	Each
6510M	SILICONE MAT	2.6 X 16.0 MAT	6510M	810051831009	Each
6511A	BASE & LID	2.6 X 16.0 X 1.5	6511A	810051830972	Each
6512A	BASE, LID & MAT	2.6 X 16.0 X 1.5	6512A	810051830965	Each
6512S	BAR, SILICONE, 1 SLOT	OPEN END ROUND-10MM SILICONE BAR	6512S	810051831474	Each

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Item-#	Description	DIMENSION IN INCHES	SKU	GTIN	Packaging Level
6515S	BAR, SILICONE, 1 SLOT	1 CUT OPEN END 16MM SILICONE BAR	6515S	810051831481	Each
6517S	BAR, SILICONE, SPECIAL CUT	DRWG. 74410	6517S	810051831498	Each
6520A	SCOPE TRAY, BASE, LID & (2) 6520S & (1) 6502S	3.0 X 22.0 X 1.5	6520A	810051831078	Each
6520B	BASE ONLY	3.0 X 22.0 X 1.5	6520B	810051831047	Each
6520L	LID ONLY	3.0 X 22.0 LID	6520L	810051831054	Each
6520M	SILICONE MAT ONLY	3.0 X 22.0 MAT	6520M	810051831061	Each
6520S	BAR, SILICONE, 2 SLOT	OPEN-13MM/CLOSED-7MM SILICONE BAR	6520S	810051831504	Each
6521A	BASE & LID	3.0 X 22.0 X 1.5	6521A	810051831030	Each
6522A	BASE, LID & MAT	3.0 X 22.0 X 1.5	6522A	810051831023	Each
6550A	BASE, LID & (4) 6501S & (2) 6502S	6.5 X 18.0 X 1.5	6550A	810051831177	Each
6550B	BASE ONLY	6.5 X 18.0 X 1.5	6550B	810051831108	Each
6550L	LID ONLY	6.5 X 18.0 LID	6550L	810051831115	Each
6550M	SILICONE MAT ONLY	6.5 X 18.0 MAT	6550M	810051831122	Each
6551A	BASE & LID	6.5 X 18.0 X 1.5	6551A	810051831092	Each
6552A	SCOPE TRAY, BASE, LID & MAT	6.5 X 18.0 X 1.5	6552A	810051831085	Each
6560A	BASE, LID & (4) 6501S & (2) 6502S	6.5 X 18.0 X 3.0	6560A	810051831184	Each
6560B	DEEP BASE ONLY	6.5 X 18.0 X 3.0	6560B	810051831153	Each

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6560M	SILICONE MAT ONLY	6.5 X 18.0 MAT	6560M	810051831160	Each
6561A	DEEP BASE & LID	6.5 X 18.0 X 3.0	6561A	810051831146	Each
6562A	DEEP BASE, LID & MAT	6.5 X 18.0 X 3.0	6562A	810051831139	Each
7000S	SILICONE BAR, BLANK, LONG	5.86 X 1.5 X 0.25 SILICONE BLANK BAR	7000S	810051831511	Each
P13189DB-1	SILICONE MAT (NON PERFORATED)	13.0 X 18.0 MAT DARK BLUE	P13189DB-1	810051831221	Each
P13189DBP	SILICONE MAT (PERFORATED)	13.0 X 18.0 MAT DARK BLUE	P13189DBP	810051831214	Each