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| MATERIAL | TYPE | ABS |
| | BRAND NAME | TERLUX 2802 HD TRASPARENT SUGGESTED STERILIZATION: ETO, GAMMA RAYS UP TO 25 KGY |
| | MANUFACTURER | STYROLUTION |

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|----------------------|---|--------------------------------|--------------------------------------|-----|
| TECHNIC. DATA | HARDNESS SHORE D (REF. ISO 868/A) | / | HARDNESS SHORE A (REF. ISO 868/A) | / |
| | VICAT SOFTENING POINT (1KG) °C (REF. ISO 306/A) | / | MELT POINT | / |
| | SPECIFIC GRAVITY (REF. ASTM TEST METHOD) D-792 | 1.08 | ELONGATION AT BREAK % (REF. ISO 527) | 12% |
| | TENSILE STRESS AT YIELD MPA (REF. ISO 527) | 48 | | |
| | FLEXURAL MODULUS MPA (REF. ISO 178) | 70 | | |
| | CAS NUMBER | 25053-09-2 9003-54-7 9011-87-4 | | |

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|--------------------|---|--|--|
| REGULATIONS | PHARMACOPOEIA | | |
| | <input checked="" type="checkbox"/> | IN COMPLIANCE WITH THE E.P. VII ED. | |
| | <input checked="" type="checkbox"/> | IN COMPLIANCE WITH THE USP CL. VI ED. | A DRUG MASTER FILE (DMF) HAS BEEN REGISTERED AT FDA FOR TERLUX 2802 HD. THE ASSIGNED DMF NUMBER IS 18074 |
| | FOOD CONTACTING MATERIALS | | |
| | <input type="checkbox"/> | ITALY: D.M. 21/3/73 AND FOLLOWING AMENDMENTS | |
| | <input checked="" type="checkbox"/> | EU: COMMISSION REGULATION NO 10/2011 | |
| | <input checked="" type="checkbox"/> | USA: CODE OF FED. REGULATION, FOOD AND DRUG ADMINISTRAT. | |
| | <input checked="" type="checkbox"/> | REACH REGULATION 1907/2006/EC | |
| | SVHC - LIST OF SUBSTANCES OF VERY HIGH CONCERN | | |
| | <input type="checkbox"/> | PHTALATES | ----- |
| | <input type="checkbox"/> | DEHPO/DOP | % |
| | <input type="checkbox"/> | NATURAL LATEX/RUBBER | |
| | <input type="checkbox"/> | BPA | |
| | <input type="checkbox"/> | | |

| | TEST | REF. | RESULTS | REPORT/DTD | LABORATORY |
|-------------------------|--|-------------|---------|------------|------------|
| CHEMICAL TEST | <input type="checkbox"/> BUFFERING CAPACITY: NaOH 0,01N | | | | |
| | <input type="checkbox"/> NONVOLATILE RESIDUE | | | | |
| | <input type="checkbox"/> RESIDUE ON IGNITION | | | | |
| | <input type="checkbox"/> HEAVY METALS | | | | |
| | <input type="checkbox"/> | | | | |
| BIOCOMPATIBILITY | <input checked="" type="checkbox"/> CITOTOXICITY IN VITRO METHOD | ISO 10993-5 | PASS | | |
| | <input type="checkbox"/> IRRITATION AND SENSITIZATION | | | | |
| | <input type="checkbox"/> INTRACUTANEOUS REACTIVITY IN THE RABBIT | | | | |
| | <input type="checkbox"/> SYSTEMIC TOXICITY (ACUTE) IN THE MOUSE | | | | |
| | <input type="checkbox"/> IMPLANTATION | | | | |
| | <input checked="" type="checkbox"/> HEMOCOMPATIBILITY: HEMOLYSIS | ISO 10993-4 | PASS | | |

LUC & BEL CODE:

M550020T

 NOTE: THE COMPLETE TEST REPORT IS AVAILABLE AT LUC&BEL PREMISES.
 DECLARATION OF CONFORMITY, RELEASED BY THE MANUFACTURER, DATED 04/11/2011 AND SUBSEQUENT



LUC&BEL S.r.l.
 Stefano Pozzetti
 R. & D. Manager