

SPECIFICATIONS
ROMED SURGICAL BLADES AND HANDLES, SCALPEL BLADES
COMPLETE WITH HANDLE
REF: SCALP-, BLADE-, HANDLE-



Applicable harmonized standard: EN 27740:1992, ISO 7740:1985
 Medical device conform MDD 93/42/EEC

Material

Blade – The steel shall conform to the following composition (Carbon steel)

<u>Constituent</u>	<u>Percent</u>
Carbon	1.10 to 1.30
Manganese	0.30 to 0.60
Chromium	0.20 to 0.50
Silicon	≤0.20
Phosphorus	≤0.03
Sulphur	≤0.03

Handle – Stainless steel conforming to designation 07Cr₁₈Ni₉.

Scalpel complete with handle – plastic handle with stainless steel blade.

The thickness of the blade shall be between 0.37 and 0.42 mm. Both surfaces of blade shall be uniform and free from roughness and waviness.

The cutting edge of the blade shall be central with respect to the thickness of the blade. The blade shall fit to the corresponding mount of the handle snugly. The blade shall be flat and shall not be sprung.

The tip of the blade shall be well defined, central and sharp. The surfaces of the blade shall be smooth and free from tool marks. The edges other than the cutting edge, shall not be sharp. Sharpness of the cutting edge shall be $\leq 0.8N$.

The handle surface shall be finished, smooth and with bright or matt finish. The handles shall be provided with suitable grips for good hold.

The blade shall be hardened and tempered to give a hardness of ≥ 700 HV for the stainless steel blades and ≥ 800 HV for the carbon steel blades. The hardness for the rest of the blade shall be not less than 500 HV.

The cutting edge of the blade has no nick of size 0.10 mm or more or two nicks of sizes between 0.05 and 0.10 mm.

Sterilisation: Gamma irradiation
Expiry date: 5 years after sterilisation



Product	Size
Scalpel blades	10, 11, 12, 15, 18, 20, 21, 22, 23, 24
Handles for scalpel blades	3, 4
Scalpels complete with handle	10, 11, 12, 15, 18, 20, 21, 22, 23, 24

Handle 3 for scalpel blades fig. 10, 11, 12, 15
Handle 4 for scalpel blades fig. 18, 20, 21, 22, 23, 24

Packing

Scalpel blades: per piece in an aluminium foil, 100 pieces in an inner box, 50 boxes in an export carton
Handles for scalpel blades: 50 pieces in an export carton
Scalpel complete with handle: sterile per piece, 10 pieces in an inner box, 50 boxes in an export carton