



To whom it may concern,

We hereby declare that PMS Steritest branded Sterilization Control Products (Indicator Strips, Bowie-Dick Test Packs, Autoclave Tapes are not considered as medical devices under the clause of MDR (EU) 2017/745.

Therefore, CE marking is not applicable and no Declaration of Conformity is issued for these products.

PMS Tıbbi Cihazlar Teknolojisi Sanayi ve Ticaret A.Ş. is the manufacturer company of the chemical indicator strip products IS2601, IS2401 and IE3501.

Taner Ersen Quality Assurance Manager

