Risk Analysis Report

Date 24/04/98

Product Tube Holders

Product Type	MDD Class I

Model Type

Product Description Tube Hoder manufactured in transparent Perspex

Manufacturer Address
Viamed Ltd.,
15 Station Road,
Crosshills
Keighley ,
West Yorkdhire BD20 7DT

We hereby declare that the statements made herein are correct and valid

Company: Viamed Ltd. 15, Station Road, Crosshills, Keighley, West Yorkshire, BD20 7DT.

Signature 

Name J.S.Lamb Director Date 13 January 1998

Ref	Hazard	Part of Equipment which pose risks	IR	Design solution Adopted	RR	Document referenced
C2	**ENERGY**					
C2.1	Electricity		4		4	
C2.2	Heat		4		4	
C2.3	Mechanical Force		4		4	
C2.4	Iononizing Radiation		4		4	
C2.5	Non Inonizing Radiation		4		4	
C2.6	Electromagnetic Fields		4		4	
C2.7	Moving Parts		4		4	
C2.8	Suspended Masses		4		4	
C2.9	Patient Support Failure		4		4	
C2.10	Pressure (Vessel rupture)		4		4	
C2.11	Acoustic pressure		4		4	
C2.12	Vibration		4		4	
C2.13	Magnetic Fields (MRI)		4		4	
C3	**BIOLOGICAL**		4		4	
C3.1	Bio-Burden		4		4	
C3.2	Bio-Contamination	Cracks	4		4	
C3.3	Bio-Incompatibility		4		4	
C3.4	Incorrect Output (Substance/energy)		4		4	
C3.5	Incorrect Formulation (Chemical Composition)		4		4	
C3.6	Toxicity		4		4	
C3.7	Cross Infection		4		4	
C3.8	Pyrogenicity		4		4	
C3.9	Inability to Maintain Hygienic Standards		4		4	
C3.10	Degradation		4		4	
C4.	**ENVIRONMENTAL**		4		4	
C4.1	Electromagnetic Interference		4		4	
C4.2	Inadequate supply of Power or Coolant		4		4	
C4.3	Likelihood of Operation outside Prescribed Environmental Conditions		4		4	

Ref.	Hazard	Part of Equipment which pose risks	I R	Design solution Adopted	R R	Document referenced
C4.4	Incompatibility with other Devices		4		4	
C4.5	Accidental Mechanical Damage	Acrylic Breaks if misused	4		4	
C4.6	Contamination due to Waste Products and or Device Disposal		4		4	
C5	**DEVICE USE**		4		4	
C5.1	Inadequate Labelling		4		4	
C5.2	Inadequate Operating Instructions		4		4	
C5.3	Inadequate Specification of Accessories		4		4	
C5.4	Inadequate Specification of Pre-Use Checks		4		4	
C5.5	Over-complicated Operating Instructions		4		4	
C5.6	Unavailable or Separated Operating Instructions		4		4	
C5.7	Use by Unskilled /untrained Personnel		4		4	
C5.8	Reasonable Foreseeable Abuse		4		4	
C5.9	Insufficient Warning of Side Effects		4		4	
C5.10	Inadequate Warnings of Hazards Likely With Re-use of Single Use Devices		4		4	
C5.11	Incorrect Measurement and other Metrological Aspects		4		4	
C5.12	Incorrect Diagnosis		4		4	
C5.13	Erroneous Data Transfer		4		4	
C5.14	Misrepresentation of Results		4		4	
			4		4	

Ref.	Hazard	Part of Equipment which pose risks	4	Design solution Adopted	4	Document referenced
C5.15	Incompatibility with Consumables /accessories / other Devices		4		4	
C6	**FUNCTIONAL FAILURE MAINTENANCE and AGEING**		4		4	
C6.1	Inadequacy of Performance Characteristics for the Intended Use		4		4	
C6.2	Lack of ,or Inadequate Specification for Maintenance including Post Maintenance Functional Tests		4		4	
C6.3	Inadequate maintenance		4		4	
C6.4	Lack of Adequate Determination of End of Device Life		4		4	
C6.5	Loss of Mechanical Integrity		4		4	
C6.6	Inadequate Packaging (contaminationand/or Deterioration of the Device)		4		4	
C6.7	Improper Use		4		4	