Risk Analysis Report

Date

Product

Product Type	MDD Class
Periferal Nerve stimulator	IIb

Model Type

Microstim DBS

Product Description

Nerve Stimulator

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 1/2/97

Ref	Hazard	Part of Equipment which pose risks	IR	Design solution Adopted	RR	Document referenced
C2	**ENERGY**		4		4	
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		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	4	Design solution Adopted	4	Document referenced
C4.4	Incompatibility with other Devices		4		4	
C4.5	Accidental Mechanical Damage		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		Design solution Adopted		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	