

PRODUCT SAFETY RISK ASSESSMENT (PSRA) REPORT

SECTION 1 – General Customer Information (Provided from customer)			
Customer Name	HILBERT MAXWELL LLC		
Customer Address			
Street	2105 Vista Oeste St NW. Suite E – 5351.		
City	Albuquerque	County	Bernalillo County
State	New Mexico	Post Code	87120
Customer Primary Contact			
Contact Name	Adolfo Benitez Herrera		
Email	adolfo@hilbertmaxwell.com		
Phone Number	+34 639 30 22 89	Fax Number	/
Economic Operators	<input checked="" type="checkbox"/> Manufacturers; <input checked="" type="checkbox"/> Importer; <input type="checkbox"/> Distributor; <input type="checkbox"/> To be decide.		
Other Information	/		

SECTION 2 – Assessment Summary	
Request	The Product Safety Risk Assessment (PSRA) accordance to Risk Assessment Guideline (RAG) incorporate with Regulation (EU) 2023/988, with consideration of specified hazards and implements Article 20 of Regulation (EC)765/2008, typical injury type and scenario, type and severity of injury, possibility again with product information collected in Section 3 “General Product Information”, compliance of products that are subject to Union harmonization legislation. (Validation of conformity on technical documents listed in Appendix F of this report is not included of this risk assessment.)
Requirement	Risk level shall not higher than “Low”.
Overall Risk Level	Choose an item. Risk.
Conclusion	The assessment satisfies the requested requirement.
<i>For details of the individual risk measurement of the hazard groups, please refer to Section 4 & Appendix A of this document.</i>	
Recommendation	/
<i>Above Assessor's opinion is for customer reference only.</i>	

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch



Arthur Mak
Authorized Signatory



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SECTION 3 – General Product Information (Provided from customer)			
Product/Concept Name	5 Mobile Phone Holder Vests Made of Synthetic Material		
Item Number	/	SKU/Style Number	i4S_Haraka1
Colours	BLACK	Size	/
Materials Used	Fabric, Plastic, Foam, Metal		
Claimed Age Labelling	<input type="checkbox"/> Not applicable. <input type="checkbox"/> On product: <Input>; <input type="checkbox"/> On packaging: <Input> <input checked="" type="checkbox"/> To be decide based on this document.		
Intended User Group	<input type="checkbox"/> Very young children (0 to 36 months (Very vulnerable consumers)) <input type="checkbox"/> Young children (Older than 36 months and younger than 8 years (Vulnerable consumers)) <input type="checkbox"/> Older children (8 to 14 years (Vulnerable consumers)) <input checked="" type="checkbox"/> Other consumers (Consumers other than vulnerable or very vulnerable consumers) <input type="checkbox"/> Vulnerable consumers (Young children. Older children. Others: persons having reduced physical, sensory or mental capabilities (e.g. partially disabled, elderly having some reduction in their physical and mental capabilities), or lack of experience and knowledge (e.g. older children)) <input type="checkbox"/> Very vulnerable consumers (Very young children. Others: persons having very extensive and complex disabilities) <input type="checkbox"/> Professional user <input type="checkbox"/> To be decide based on this document.		
Intended Genders of User Group	<input checked="" type="checkbox"/> No specify; <input type="checkbox"/> If have, please specify <Input> <input type="checkbox"/> To be decide based on this document.		
Intended / Reasonably Foreseeable Use	<input checked="" type="checkbox"/> To be decide based on this document.		
Assembly/Installation	<input checked="" type="checkbox"/> Preassembled/Installed; <input type="checkbox"/> Required by user; <input type="checkbox"/> Required by service provider		
Trademarked Product	<input type="checkbox"/> No; <input type="checkbox"/> Yes, Trademark name: Ingenium for Sports		
Product URL	https://ingeniumforsports.com/running/		
Product Status	<input checked="" type="checkbox"/> New; <input type="checkbox"/> Modified; <input type="checkbox"/> Repaired; <input type="checkbox"/> Reconditioned; <input type="checkbox"/> Recycled		
Countries of Distribution	European Union	Country of Manufacture	China
Product Image/Photo	<div> <input type="checkbox"/> Photo provided from customer. <input checked="" type="checkbox"/> Photo taken from received sample. </div> 		



PRODUCT SAFETY RISK ASSESSMENT (PSRA) REPORT

SECTION 4 – Overall Rating by Product Hazard

(Details the severity of harm and the probability of occurrence of the harm in the scenario, please refer to Appendix A "Details of assessment")

Hazard groups	Risk level	Assessment findings
Size, shape and surface	Low	Injure: Laceration, cut Findings: Metal components may have sharp points/sharp edges <input checked="" type="checkbox"/> Risk Reduction: Passing sharp point/ sharp edge test as per EN 71-1, the risk is shown to be medium to low. (Supporting information for above assessment details A1.1)
Potential energy	/	/
Kinetic energy	Low	Injure: Findings: User wearing the vest is hit by moving vehicle when running in dark environment wearing this vest whose reflective area is not sufficient to comply with the requirement of EN 17353 for middle risk level <input checked="" type="checkbox"/> Risk Reduction: The manufacturer added below warnings at the advertising material: "This product features reflective material ideal for low-risk everyday situations, such as recreational activities, but it is not designed for high-risk situations like road work or nighttime cycling in heavy traffic areas. This vest has not been designed to meet the requirements of Class II Personal Protective Equipment (PPE), which is intended for protection in more hazardous environments.", the risk is shown to be medium to low. (Supporting information for above assessment details A1.3)
Electrical energy	/	/
Extreme temperatures	/	/
Radiation	/	/
Fire and explosion	Low	Injure: Burn Findings: Textile and foam which compose of over 90% of the total weight of the product may catches fire by flaming source, user may get burned by open flame once the vest catches fire. <input checked="" type="checkbox"/> Risk Reduction: Conducting flammability test of solid against 16 CFR 1500.44, with burning rat of less than 0.15 inch/ second, the risk is shown to be medium to low. (Supporting information for above assessment details A1.2)
Toxicity	Low	Injure: Long-term damage from contact with t CMR substances Findings: , product may contain toxic and CMR substances <input checked="" type="checkbox"/> Risk Reduction: <Test report shows no toxic and CMR substances were found. The risk shows from medium to low>
	Low	Injure: Allergic reaction and sensation Findings: the product contains metal, natural rubber, foam and glue, which may contain sensitising substances and leach to skin during actual usage. <input checked="" type="checkbox"/> Risk Reduction: <Test report shows no nickle release, and product was not supposed to contact skin in long term, the risk is shown to be medium to low >
Microbiological contamination	/	/
Product operating hazards	/	/

Details of hazard, typical injury scenario, typical injury, type of injury and assessment data, please refer to Appendix A.

This assessment does not cover when the risk assessment requirement specified in relevant Regulation or European harmonized standards shown in Appendix E of this document.



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Appendix A, Details of assessment

PRODUCT HAZARD		HOW THE HAZARD CAUSES AN INJURY TO THE CONSUMER	SEVERITY OF INJURY	OBSERVATION			ESTIMATION	
Hazard group	Hazard (product property)	Typical injury scenario	Typical injury	Type of injury	Severity of injury	Possibility	Risk of this scenario	Note
Size, shape and surface	Sharp corner or point	Person hits sharp corner or is hit by moving sharp object; this causes a puncture or penetration injury	Laceration, cut;	Laceration, cut;	Superficial	Practically impossible	Low	No sharp point is found
Size, shape and surface	Sharp edge	Person touches sharp edge; this lacerates skin or cuts through tissues	Laceration, cut;	Laceration, cut;	Superficial	Practically impossible	Low	No sharp point is found
Kinetic energy	Moving product	User hit by moving vehicle when running in dark environment wearing this vest.	Concussion; crushing	Concussion	Prolonged unconsciousness	Impossible unless aided	Low	With warning: "This product features reflective material ideal for low-risk everyday situations, such as recreational activities, but it is not designed for high-risk situations like road work or nighttime cycling in heavy traffic areas. This vest has not been designed to meet the requirements of Class II Personal Protective Equipment (PPE), which is intended for protection in more hazardous environments."
Fire and explosion	Flammable substances	Person is wearing the flammable substance; an ignition source sets the substance to fire; this causes injuries to the person	Burn	Burn	2°, 6-15% of body surface	Practically impossible	Low	Burn rate of less than 0.15 inch/second when test with 16 CFR 1500.44
Toxicity	CMR substance	User sweating lead to leaching of harmful substance: such as BPA, PFAS,	Long-term damage from contact with substances or from exposure to	Harmful substance enter into body by skin;	Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia	Unusual but possible	Low	avoid direct contact skin by long-term



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PRODUCT HAZARD		HOW THE HAZARD CAUSES AN INJURY TO THE CONSUMER	SEVERITY OF INJURY	OBSERVATION			ESTIMATION	
Hazard group	Hazard (product property)	Typical injury scenario	Typical injury	Type of injury	Severity of injury	Possibility	Risk of this scenario	Note
			radiation					
Toxicity	Irritating gas or vapour	Higher body temperature lead to irritating gas releasing	Eye or nose irritation	Eye or nose irritation	Local slight irritation	Practically impossible	Low	The product has strong odor. VOC test may request (Ventilation before use)
Toxicity	Irritating solid	User sweating lead to leaching of harmful substance:	irritation, dermatitis; skin burn;	irritation, dermatitis; skin burn;	Local slight irritation	Conceivable but highly unlikely	Low	Foam and glue is employed in this product
Toxicity	Sensitising substance	User sweating lead to leaching of harmful substance:	Sensitisation; allergic reaction	irritation, dermatitis; skin burn;	Mild an local allergic reaction	Unusual but possible	Low	Natural rubber are employed in this product, but the product was not for contact to skin in long term.


Supporting information for above assessment details:

#	Picture/Image	Comment
A1.1		Sharp points/ sharp edges are not found from metal/ rigid parts.



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A1.2		The sample is tested with solid flammability test as per 16 CFR 1500.44
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A1.3	 <p>Chaleco Running i4S Haraka 1 Unisex. Porta teléfono y Llaves, Reflectante y Porta Luces. Ingenium for Sports. Accesorio Multideporte como Running, Caminar o...</p> <p>Inicio Running Tenis de mesa Contacto</p> <p>Todos nuestros productos, antes de enviarlos, reciben una inspección completa por una empresa externa en la fábrica en China.</p> <p>(*) Este producto cuenta con material reflectante ideal para situaciones cotidianas de bajo riesgo, como actividades recreativas, pero no está diseñado para situaciones de alto riesgo como, por ejemplo, trabajos en carretera o rodar en bicicleta por la noche en áreas de tráfico intenso. Este chaleco no ha sido diseñado para cumplir con los requisitos de la Categoría II de Equipos de Protección Individual (EPI), que están destinados a la protección en entornos más peligrosos.</p> <p>(Real Decreto 773/1997)</p>	Website content
A1.4		



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PRODUCT SAFETY RISK ASSESSMENT (PSRA) REPORT

Appendix B, Injury scenario and its severity of injury

PRODUCT HAZARD		HOW THE HAZARD CAUSES AN INJURY TO THE CONSUMER	SEVERITY OF INJURY
Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
Size, shape and surface	Product is obstacle	Person trips over product, falls and hits the floor; or person bumps into product	Bruising; fracture, concussion
	Product is impermeable to air	Product covers mouth and/or nose of a person (typically a child) , or covers internal airway	Suffocation
	Product is or contains small part	Person (child) swallows small part; the part gets stuck in larynx and blocks airways	Choking, internal airway obstruction
	Sharp corner or point	Person hits sharp corner or is hit by moving sharp object; this causes a puncture or penetration injury	Puncture; blinding, foreign body in eye; hearing, foreign body in ear
	Sharp edge	Person touches sharp edge; this lacerates skin or cuts through tissues	Laceration, cut; amputation
	Slippery surface	Person walks on surface, slips and falls hitting the floor	Bruising; fracture, concussion
	Rough surface	Person slides along rough surface; this causes friction and/or abrasion	Abrasion
	Gap or opening between parts or elements	Person puts a limb or body in opening and is trapped with finger, arm, neck, head, body or clothing; injury occurs due to gravity or movement	Crushing, fracture, amputation, strangulation
	Possibility to bite off small part from product	Person (child) swallows small part; the part gets stuck in the digestive tract	Digestive tract obstruction
Potential energy	Low mechanical stability	Product tips; person on top of product falls from height, or person near product is hit by the product; electrical product tips, break and gives access to live parts, or continues to work heating nearby surfaces	Bruising; dislocation; sprain; fracture, concussion; crushing; electric shock; burns
	Low mechanical strength	Product collapses by overloading; person on top of product falls from height, or person near product is hit by the product; electrical product tips, break and gives access to live parts, or continues to work heating nearby surfaces	Bruising; dislocation; fracture, concussion; crushing; electric shock; burns
	High position of user	Person at high position on the product loses balance, has no support to hold on to and falls from height	Bruising; dislocation; fracture, concussion; crushing
	Elastic element or spring	Elastic element or spring under tension is suddenly released; person in the line of movement is hit by the product	Bruising; dislocation; fracture, concussion; crushing
	Pressurised liquid or gas, or vacuum	Liquid or gas under pressure is suddenly released; person in the vicinity is hit; or implosion of the product produces flying objects	Dislocation; fracture, concussion; crushing; cuts (see also under fire and explosion)
Kinetic energy	Moving product	Person in the line of movement of the product is being hit by the product or run over	Bruising; sprain; fracture, concussion; crushing
	Parts moving against one another	Person puts a body part between the moving parts while they move together; the body part gets trapped and put under pressure (crushed)	Bruising; dislocation; fracture, concussion; crushing
	Parts moving past one another	Person puts a body part between the moving parts while they move close by (scissor movement); the body part gets trapped between the moving parts and put under pressure (shearing)	Laceration, cut; amputation
	Rotating parts	A body part, hair or clothing of a person is entangled by the rotating part; this causes a pulling force	Bruising; fracture; laceration (skin of the head); strangulation
	Rotating parts close to one another	A body part, hair or clothing of a person is drawn in by the rotating parts; this causes a pulling force and pressure on the body part	Crushing, fracture, amputation, strangulation
	Acceleration	Person on the accelerating product loses balance, has no support to hold on to and falls with some speed	Dislocation; fracture, concussion; crushing
	Flying objects	Person is hit by the flying object and depending on the energy sustains injuries	Bruising; dislocation; fracture, concussion; crushing
	Vibration	Person holding the product loses balance and falls; or prolonged contact with vibrating product causes	Bruising; dislocation; fracture, concussion; crushing



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Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
Electrical energy	Noise	neurological disorders, osteo-articular disorder, trauma of the spine, vascular disorder Person is exposed to noise from the product. Tinnitus and hearing loss may occur depending on sound level and distance	Hearing injury
	High/low voltage	Person can touch part of the product that is at high voltage; the person receives an electric shock and may be electrocuted	Electric shock
	Heat production	Product becomes hot; a person touching it may sustain burns; or the product may emit molten particles, steam etc. that hits a person	Burn, scald
	Live parts too close	Electric arc or sparks occur between the live parts. This may cause a fire and intense radiation	Eye injury; burn, scald
Extreme temperatures	Open flames	A person near the flames may sustain burns, possibly after clothing catches fire	Burn, scald
	Hot surfaces	Person does not recognise the hot surface and touches it; the person sustains burns	Burn
	Hot liquids	Person handling a container of liquid spills some of it; the liquid falls on the skin and causes scalds	Scald
	Hot gases	Person breathes in the hot gases emitted from a product; this causes lung burn; or prolonged exposure to hot air causes dehydration	Burn
	Cold surfaces	Person does not recognise the cold surface and touches it; the person sustains frostbite	Burn
Radiation	Ultraviolet radiation	Skin or eyes of a person are exposed to radiation emitted by the product	Burn, scald; neurological disorders; eye injury; skin cancer, mutation
	High intensity electromagnetic field (EMF) source; low frequency or high frequency (microwave)	Person is close to the electromagnetic field (EMF) source, body (central nervous system) is exposed	Neurological (brain) damage, Leukemia (children)
Fire and explosion	Flammable substances	Person is near the flammable substance; an ignition source sets the substance to fire; this causes injuries to the person	Burn
	Explosive mixtures	Person is near the explosive mixture; an ignition source causes an explosion; the person is hit by the shock wave, burning material and/or flames	Burn, scald; eye injury, foreign body in eye; hearing injury, foreign body in ear
	Ignition sources	The ignition source causes a fire; a person is injured by flames, or intoxicated by gases from the house fire	Burn; poisoning
	Overheating	Product overheats; fire, explosion	Burn, scald; eye injury, foreign body in eye; hearing injury, foreign body in ear
Toxicity	Toxic solid or fluid	Person ingests substance from product, e.g. by putting it in mouth, and/or substance gets on skin. Person breathes in solid or fluid, for example vomited material (pulmonary aspiration).	Acute poisoning; irritation, dermatitis
	Toxic gas, vapour or dust	Person inhales substance from product; and/or substance gets onto skin	Acute poisoning in lungs; irritation, dermatitis
	Sensitising substance	Person ingests substance from product, e.g. by mouthing; and/or substance gets onto skin; and/or person inhales gas, vapour or dust	Sensitisation; allergic reaction
	Irritating or corrosive solid or fluid	Person ingests substance from product, e.g. by putting it in mouth, and/or substance gets onto skin; and/or person inhales substance as gas, vapour or dust	Irritation, dermatitis; skin burn; eye injury, foreign body in eye
	Irritating or corrosive gas or vapour	Person inhales substance from product; and/or substance gets onto skin or in eyes	Irritation, dermatitis; skin burn; acute poisoning or corrosive effect in lungs or in eyes
	CMR substance	Person ingests substance from product, e.g. by mouthing; and/or substance gets onto skin; and/or person inhales gas, vapour or dust	Cancer, mutation, reproductive toxicity



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Hazard group	Hazard (product property)	Typical injury scenario	Typical injury
Microbiological contamination	Microbiological contamination	Person gets into contact with contaminated product by ingestion, inhalation or skin contact	Infection, local or systemic
Product operating hazards	Unhealthy posture	Design causes unhealthy posture of person when operating the product	Strain; musculoskeletal disorder
	Overexertion	Design requires use of considerable force when operating the product	Sprain or strain; musculoskeletal disorder
	Anatomical unsuitability	Design is not adapted to human anatomy which makes it difficult or impossible to operate	Sprain or strain
	Ignoring personal protection	Design makes it difficult for a person wearing protection to handle or operate the product	Various injuries
	Inadvertent (de)activation	Person can easily (de)activate product which leads to unwanted operation	Various injuries
	Operational inadequacy	Design provokes faulty operation by a person; or product with a protective function does not provide expected protection	Various injuries
	Failure to stop	Person wants to stop the product, but it continues to operate in situation where this is unwanted	Various injuries
	Unexpected start	Product shuts down during a power failure, but resumes operation in a hazardous way	Various injuries
	Inability to stop	In an emergency situation, person is not able to stop operation of the product	Various injuries
	Inadequately fitting parts	Person tries to fit a part, needs too much force to fit, product breaks; or part is too loosely fitted and gets loose during use	Sprain or strain; laceration, cut; bruising; entrapment
	Missing or incorrectly fitted protection	Hazardous parts are reachable for a person	Various injuries
	Insufficient warning texts and symbols	User does not notice warning texts and/or does not understand symbols	Various injuries
	Insufficient warning signals	User does not see or hear warning signal (optical or auditive) causing dangerous operation	Various injuries

Appendix C, Severity of injury level

Type of injury	Severity of injury			
	1	2	3	4
Allergic reaction or sensitisation	Mild an local allergic reaction	Allergic reaction, widespread allergic contact dermatitis	Strong sensitisation, provoking allergies to multiple substances	Anaphylactic reaction, shock; Fatality
Amputation	/	/	Finger(s); Toe(s); Hand; Foot; (Part of) Arm; Leg; Eye	Both extremities
Bruising (abrasion/ contusion, swelling, oedema)	Superficial; =25 cm² on face; =50 cm² on body	Major; >25 cm² on face; >50 cm² on body	Trachea; Internal organs (minor); Heart; Brain; Lung, with blood or air in chest	Brain stem; Spinal cord causing paralysis
Burn/ Scald (by heat, cold, or chemical substance)	1°, up to 100% of body surface; 2°, <6% of body surface	2°, 6-15% of body surface	2°, 16-35% of body surface, or 3°, up to 35% of body surface; Inhalation burn	2° or 3°, >35% of body surface; Inhalation burn requiring respiratory assistance
Concussion	/	Very short unconsciousness (minutes)	Prolonged unconsciousness	Coma
Crushing	/	/	Extremities (fingers, toe, hand, foot); Elbow; Ankle; Wrist; Forearm; Leg; Shoulder; Trachea; Larynx; Pelvis	Spinal cord; Mid-low neck; Chest (massive crushing); Brain stem
Dislocation	/	Extremities (finger, toe, hand, foot); Elbow; Jaw; Loosening of tooth	Ankle; Wrist; Shoulder; Hip; Knee; Spine	Spinal column



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Type of injury	Severity of injury			
	1	2	3	4
Electric shock	(see also under burns as electric current can cause burns)	Local effects (temporary cramp or muscle paralysis)	/	Electrocution
Entrapment/ pinching	Minor pinching	/	(refer to the final outcomes bruising, crushing, fracture, dislocation, amputation, as applicable)	(refer to Suffocation / Strangulation)
Eye injury, foreign body in eye	Temporary pain in eye without need for treatment	Temporary loss of sight	Partial loss of sight; Permanent loss of sight (one eye)	Permanent loss of sight (both eyes)
Fracture	/	Extremities (finger, toe, hand, foot); Wrist; Arm; Rib; Sternum; Nose; Tooth; Jaw; Bones around eye	Ankle; Leg (femur and lower leg); Hip; Thigh; Skull; Spine (minor compression fracture); Jaw (severe); Larynx; Multiple rib fractures; Blood or air in chest	Neck; Spinal column
Hearing injury, foreign body in ear	Temporary pain in ear without need for treatment	Temporary impairment of hearing	Partial loss of hearing; Complete loss of hearing (one ear)	Complete loss of hearing (both ears)
Ingestion	/	/	Internal organ injury (Refer also to internal airway obstruction in case the ingested object gets stuck high in the oesophagus.)	Permanent damage to internal organ
Internal airway obstruction	/	/	Oxygen flow to brain blocked without permanent consequences	Oxygen flow to brain blocked with permanent consequences
Irritation, dermatitis, inflammation or corrosive effect of substances (inhalation, dermal)	Local slight irritation	Reversible eye damage; Reversible systemic effects; Inflammatory effects	Lungs, respiratory insufficiency, chemical pneumonia; Irreversible systemic effects; Partial loss of sight; Corrosive effects	Lungs, requiring respiratory assistance; Asphyxia
Laceration, cut	Superficial	External (deep) (>10cm long on body); (>5cm long on face) requiring stitches; Tendon or into joint; White of eye or Cornea	Optic nerve; Neck artery; Trachea; Internal organs	Bronchial tube; Oesophagus; Aorta; Spinal cord (low); Deep laceration of internal organs; Severed high spinal cord; Brain (severe lesion/dysfunction)
Long-term damage from contact with substances or from exposure to radiation	Diarrhoea, vomiting, local symptoms	Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia	Damage to nerve system, e.g. Organic Psycho Syndrome (OPS; or Uremic Toxic Encephalopathy, also known as "painter disease"). Irreversible damage to internal organs, e.g. oesophagus, stomach, liver, kidney, haemolytic anaemia, reversible damage to nerve system	Cancer (leukaemia); Effects on reproduction; Effects on offspring; CNS depression
Microbiological infection	/	Reversible damage	Irreversible effects	Infection requiring prolonged hospitalisation, antibiotics resistant organisms; Fatality
Neurological disorders	/	/	Triggered epileptic seizure; Neurological effects of EMF	/
Piercing, puncturing	Limited depth, only skin involved	Deeper than skin; Abdominal wall (no organ involvement)	Eye; Internal organs; Chest wall	Aorta; Heart Bronchial Tube; Abdominal organs (liver, kidney, bowel, etc) Deep



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Type of injury	Severity of injury			
	1	2	3	4
Poisoning from substances (ingestion, inhalation, dermal)	Diarrhoea, vomiting, local symptoms	Reversible damage to internal organs, e.g. liver, kidney, slight haemolytic anaemia	Irreversible damage to internal organs, e.g. oesophagus, stomach, liver, kidney, haemolytic anaemia, reversible damage to nerve system	Irreversible damage to nerve system; Fatality
Sprain, strain, musculoskeletal disorder	Extremities; Joints; Spine (no dislocation or fracture)	Knee ligaments strain	Ligament or tendon rupture/ tear; Muscle tear; Whiplash	/
Submersion / Drowning	/	/	/	Fatal drowning
Suffocation / Strangulation	/	/	Oxygen flow to brain blocked without permanent consequences	Fatal suffocation / strangulation
Other	/	/	/	/

The above table, which should be considered as a guide rather than prescriptive or complete, provides examples of injuries at all four levels. National differences may exist, either cultural or caused by different systems of health care and financial arrangements. However, deviating from the proposed classification in the table will affect uniform assessment of risks in the EU; this should be clearly stated and explained in the risk assessment report, and reasons should be given.

Appendix D, Risk level from the combination of the severity of injury and probability

Probability of damage during foreseeable lifetime of the product		Severity of Injury			
Possibility		1	2	3	4
Almost certain might well be expected	>50%	High Risk	Serious Risk	Serious Risk	Serious Risk
Quite possible	>1/10	Medium Risk	Serious Risk	Serious Risk	Serious Risk
Unusual but possible	>1/100	Medium Risk	Serious Risk	Serious Risk	Serious Risk
Only remotely possible	>1/1,000	Low Risk	High Risk	Serious Risk	Serious Risk
Conceivable but highly unlikely	>1/10,000	Low Risk	Medium Risk	High Risk	Serious Risk
Practically impossible	>1/100,000	Low Risk	Low Risk	Medium Risk	High Risk
Impossible unless aided	>1/1,000,000	Low Risk	Low Risk	Low Risk	Medium Risk
Impossible	<1/1,000,000	Low Risk	Low Risk	Low Risk	Low Risk

Severity of Injury:

Four levels of severity have been identified in the Risk Assessment Guide (RAG):

- Injury or consequences that after basic treatment (First aid, normally not by a doctor) does not substantially hamper the functioning or cause excessive pain; usually the consequences are completely reversible.
Harm: Negative effect, usually completely reversible within the short term without specialist intervention.
- Injury or consequence for which a visit to the Emergency Room may be necessary, but in general hospitalization is not required. The functioning may be affected for a limited time, not more than about 6 months, and recovery is more or less complete.
Harm: Negative effect, reversible within a certain period, specialist intervention is required.
- Injury or consequence that normally requires hospitalization and will affect functioning for more than 6 months or lead to permanent loss of function.
Harm: Significant negative effect only in the longer term, significant effort to reverse by specialist intervention, irreversible without this intervention and effort.
- Injury or consequence that is or could be fatal, including brain death; consequences that affect reproduction of offspring; severe / grievous loss of limbs and / or function, leading to more than about 10% disability.
Harm: Large negative effect, irreversible in several aspects, whether or not acute.

Appendix E, Uncertainty concerning risk assessment

Principal of the uncertainty for the risk level during risk assessment
<p>The risk level is a final stage of the assessment process is to combine the severity of harm and the probability of occurrence of the harm in the scenario described in Appendix A "Details of assessment", the severity of injury described in Appendix B "Severity of injury level", and the probability of the occurrence of the harm described in Appendix C "Risk level from the combination of the severity of injury and probability".</p> <p>The risk level "Serious" mentioned in this document is consistent with Article 20 of Regulation 765/2008/EC, and the other 3 risk levels is reference to Article R31 of Decision 768/2008.</p> <p>The uncertainty is expected to be reduced as more information becomes available, upper confidence zone will be considerate when uncertainty present during the assessment.</p> <p>The usage of this assessment shall be in the pre-cautionary principle.</p>



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 - The service provides from Economic operators.
 - Obligations of Economic Operators, Trader, Responsible person for products placed outside the Union market.
 - Activity for distance selling, including online selling activity.
 - Cybersecurity risk, transportation, warehouse and shelves/stock life before sold to customer.
 - Product Safety Pledge, Financing activities from the Economic Operators, Trader.
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