



**INTEGRA96 ULUSLARARASI URUN VE SISTEM
BELGELENDİRME, BAGIMSIZ GOZETİM, DENETİM, EGİTİM
HİZMETLERİ LTD. STİ.**

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**2006/42/EC CONFORMITY REPORT
EN ISO 12100:2010**

**Safety of machinery- General principles for design-
Risk assessment and risk reduction (ISO 12100:2010)**

Manufacturer	MAY BESA ENERJİ İKLİMLENDİRME MAKİNA İNŞAAT TAAHHÜT SANAYİ TİCARET LİMİTED ŞİRKETİ		
Adress.....	Kazım Karabekir Mah. Bekir Saydam Cad. No: 54 / 3B Torbalı / İzmir/ TÜRKİYE		
Product / Model(s)	Ozon Jeneratörü - eszo/97s Ozone Generator - eszo/97s		
Report Number	TRM-20-2149/03		
Date of issue.....	22.10.2020		
Standard	EN ISO 12100:2010		
Number of pages (Report).....	08		
Number of pages	-		
Compiled by.....	Eng. C. HURSI TOGLU	Approved by.....	Eng. C. HURSI TOGLU
(+ signature)		(+ signature)	
test case does not apply to the test object.....			N/A
test object does meet the requirement.....			P(ass)
test object does not meet the requirement.....			F(ail)
General Remarks			

The variants (Esb/se, Esb/e, Esv/_e, ebe/air, Esb/e, eszo/97, eszo/98s, eszo/98/plus, esz/oxy, esz/t) were analyzed and verified similar to the tested one (In electrical characteristic, all models mentioned above are similar, the difference among them are appearance and rated input power). The difference has no impact on the safety characteristics, then the result of this test report are valid for all models.

"(see remark #)" refers to a remark appended to the report.

"(see appended table)" refers to a table appended to the report.

Through out this report a comma is used as the decimal separator.

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Report No.: TRM-20-2149/03

Page 2/8

EN ISO 12100: Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)

Clause	Requirement	Result Remark	Verdict
1	Scope		
2	Normative references		
3	Terms and definitions		
4	Stragety for risk assasment and risk reduction		
5	Risk Assessment		
5.1	General Risk analysis provides information required for the risk evaluation, which in turn allows judgments to be made about whether or not risk reduction is required. These judgments shall be supported by a qualitative or, where appropriate, quantitative estimate of the risk associated with the hazards present on the machinery.	✓ <i>These principles have been taken into designation and produce.</i>	PASS
5.2	Information for Risk Assesment The information for risk assessment should include the following. - Related to machinery description - Related to regulations, standards and other applicable documents - Related to experience of use - Relevant ergonomic principles.	✓ <i>see operation manual</i>	PASS
5.3	Determination of limits of machinery	✓	PASS
5.3.1	General Risk assessment begins with the determination of the limits of the machinery, taking into account all the phases of the machinery life. This means that the characteristics and performances of the machine or a series of machines in an integrated process, and the related people, environment and products, should be identified in terms of the limits of machinery as given in 5.3.2 to 5.3.5.	✓	PASS
5.3.2	Use Limits Use limits include the intended use and the reasonably foreseeable misuse. Aspects to be taken into account include the following: a) the different machine operating modes and different intervention procedures for the users, including interventions required by malfunctions of the machine; b) the use of the machinery (for example, industrial, non-industrial and domestic) by persons identified by sex, age, dominant hand usage, or limiting physical abilities (visual or hearing impairment, size, strength,	✓ <i>see operation manual</i>	PASS

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Report No.: TRM-20-2149/03

Page 3/8

EN ISO 12100: Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)

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	<p>etc.); c) the anticipated levels of training, experience or ability of users including 1) operators, 2) maintenance personnel or technicians, 3) trainees and apprentices, and 4) the general public; d) exposure of other persons to the hazards associated with the machinery where it can be reasonably foreseen: 1) persons likely to have a good awareness of the specific hazards, such as operators of adjacent machinery; 2) persons with little awareness of the specific hazards but likely to have a good awareness of site safety procedures, authorized routes, etc., such as administration staff; 3) persons likely to have very little awareness of the machine hazards or the site safety procedures, such as visitors or members of the general public, including children. If specific information is not available in relation to b), above, the manufacturer should take into account general information on the intended user population (for example, appropriate anthropometric data). - parts which have become live under fault conditions, especially as a result of an insulation failure(indirect contact); - approach of persons to live parts, especially in the range of high voltage; - insulation not suitable for reasonably foreseeable conditions of use; - electrostatic phenomena such as contact of persons with charged parts - thermal radiation; - phenomena such as projection of molten particles or chemical effects from short-circuits or overloads. It can also cause falls of persons (or of objects dropped by persons) as a result of the surprise caused by electric shock.</p>		
5.3.3	<p>Space Limits Aspects of space limits to be taken into account include a) the range of movement, b) space requirements for persons interacting with the machine, such as during operation and maintenance, c) human interaction such as the operator-machine interface, and d) the machine-power supply interface.</p>	✓	PASS

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Report No.: TRM-20-2149/03

Page 4/8

EN ISO 12100: Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)

Clause	Requirement	Result Remark	Verdict
5.3.4	Time Limits Aspects of time limits to be taken into account include a) the life limit of the machinery and/or of some of its components (tooling, parts that can wear, electromechanical components, etc.), taking into account its intended use and reasonably foreseeable misuse, and b) recommended service intervals.	✓	PASS
5.3.5	Other Limits Examples of other limits include a) properties of the material(s) to be processed, b) housekeeping — the level of cleanliness required, and c) environmental — the recommended minimum and maximum temperatures, whether the machine can be operated indoors or outdoors, in dry or wet weather, in direct sunlight, tolerance to dust and wet, etc.	✓	PASS
5.4	Hazard identification After determination of the limits of the machinery, the essential step in any risk assessment of the machinery is the systematic identification of reasonably foreseeable hazards (permanent hazards and those which can appear unexpectedly), hazardous situations and/or hazardous events during all phases of the machine life cycle, i.e.: — transport, assembly and installation; — commissioning; — use; — dismantling, disabling and scrapping. Only when hazards have been identified can steps be taken to eliminate them or to reduce risks. To accomplish this hazard identification, it is necessary to identify the operations to be performed by the machinery and the tasks to be performed by persons who interact with it, taking into account the different parts, mechanisms or functions of the machine, the materials to be processed, if any, and the environment in which the machine can be used. The designer shall identify hazards taking into account the following. - Human interaction during the whole life cycle of the machine - Possible states of the machine - Unintended behaviour of the operator or reasonably foreseeable misuse of	✓ <i>see operation manual</i>	PASS

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Report No.: TRM-20-2149/03

Page 5/8

EN ISO 12100: Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)

Clause	Requirement	Result Remark	Verdict
	the machine		
5.5	Risk estimation		
5.5.1	General hazard identification, risk estimation shall be carried out for each hazardous situation by determining the elements of risk given in 5.5.2. When determining these elements, it is necessary to take into account the aspects given in 5.5.3. If standardized (or other suitable) measurement methods exist for an emission, they should be used, in conjunction with existing machinery or prototypes, to determine emission values and comparative emission data. This makes it possible for the designer to Hazards other than emissions that are described by measurable parameters can be dealt with in a similar manner.	✓	PASS
5.5.2	Elements of risk		
5.5.2.1	General The risk associated with a particular hazardous situation depends on the following elements: a) the severity of harm; b) the probability of occurrence of that harm, which is a function of 1) the exposure of person(s) to the hazard, 2) the occurrence of a hazardous event, and 3) the technical and human possibilities to avoid or limit the harm. The elements of risk are shown in Figure 3. Additional details are given in 5.5.2.2, 5.5.2.3 and 5.5.3..	✓	PASS
5.5.2.2	Severity of harm When carrying out a risk assessment, the risk from the most likely severity of the harm that is likely to occur from each identified hazard shall be considered, but the highest foreseeable severity shall also be taken into account, even if the probability of such an occurrence is not high.	✓	PASS
5.5.2.3	Probability of occurrence of harm		
5.5.2.3.1	Exposure of persons to the hazard The exposure of a person to the hazard influences the probability of the occurrence of harm. Factors to be taken into account when estimating the exposure are, among others, a) the need for access to the hazard zone (for normal operation, correction	✓	PASS

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Report No.: TRM-20-2149/03

Page 6/8

EN ISO 12100: Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)

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	of malfunction, maintenance or repair, etc.), b) the nature of access (for example, manual feeding of materials), c) the time spent in the hazard zone, d) the number of persons requiring access, and e) the frequency of access.		
5.5.2.3.2	Occurrence of a hazardous event The occurrence of a hazardous event influences the probability of occurrence of harm. Factors to be taken into account when estimating the occurrence of a hazardous event are, among others, a) reliability and other statistical data, b) accident history, c) history of damage to health, and d) comparison of risks (see 5.6.3).	✓	PASS
5.5.2.3.3	Possibility of avoiding or limiting harm The possibility of avoiding or limiting harm influences the probability of occurrence of harm. Factors to be taken into account when estimating the possibility of avoiding or limiting harm are, among others, the following: a) different persons who can be exposed to the hazard(s), b) how quickly the hazardous situation could lead to harm c) any awareness of risk, d) the human ability to avoid or limit harm (for example, reflex, agility, possibility of escape) e) practical experience and knowledge	✓	PASS
5.5.3	Aspects to be considered during risk estimation		
5.5.3.1	Persons exposed Risk estimation shall take into account all persons (operators and others) for whom exposure to the hazard is reasonably foreseeable	✓	PASS
5.5.3.2	Type, frequency and duration of exposure The estimation of the exposure to the hazard under consideration (including long-term damage to health) requires analysis of, and shall account for, all modes of operation of the machinery and methods of working. In particular, the analysis shall account for the needs for access during loading/unloading, setting, teaching, process changeover or correction, cleaning, fault-finding and maintenance.	✓	PASS

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Page 7/8

EN ISO 12100: Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)

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	The risk estimation shall also take into account tasks, for which it is necessary to suspend protective measures.		
5.5.3.3	Relationship between exposure and effects The relationship between an exposure to a hazard and its effects shall be taken into account for each hazardous situation considered. The effects of accumulated exposure and combinations of hazards shall also be considered. When considering these effects, risk estimation shall, as far as practicable, be based on appropriate recognized data.	✓	PASS
5.5.3.4	Human Factors Training, experience and ability can affect risk; nevertheless, none of these factors shall be used as a substitute for hazard elimination, risk reduction by inherently safe design measure or safeguarding, wherever these protective measures can be practicably implemented.	✓	PASS
5.5.3.5	Suitability of protective measures Risk estimation shall take into account the suitability of protective measures and shall a) identify the circumstances which can result in harm, b) whenever appropriate, be carried out using quantitative methods to compare alternative protective measures (see ISO/TR 14121-2), and c) provide information that can assist with the selection of appropriate protective measures. When estimating risk, those components and systems identified as immediately increasing the risk in case of failure need special attention. When protective measures include work organization, correct behaviour, attention, application of personal protective equipment (PPE), skill or training, the relatively low reliability of such measures compared with proven technical protective measures shall be taken into account in the risk estimation.	✓	PASS
5.5.3.6	Possibility of defeating or circumventing protective measures For the continued safe operation of a machine, it is important that the protective measures allow its easy use and do not hinder its intended use. Otherwise, there is a possibility that protective measures might be	✓	PASS

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Page 8/8

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	<p>bypassed in order for maximum utility of the machine to be achieved. Risk estimation shall take account of the possibility of defeating or circumventing protective measures. It shall also take account of the incentive to defeat or circumvent protective measures when, for example,</p> <p>a) the protective measure slows down production or interferes with another activity or preference of the user, b) the protective measure is difficult to use, c) persons other than the operator are involved, or d) the protective measure is not recognized by the user or not accepted as being suitable for its function.</p> <p>Whether or not a protective measure can be defeated depends on both the type of protective measure, such as an adjustable guard or programmable trip device, and its design details. Protective measures that use programmable electronic systems introduce additional possibilities of defeat or circumvention if access to safety-related software is not appropriately restricted by design and monitoring methods. Risk estimation shall identify where safety-related functions are not separated from other machine functions and shall determine the extent to which access is possible. This is particularly important when remote access for diagnostic or process correction purposes is required.</p>		
5.5.3.7	<p>Ability to maintain protective measures Risk estimation shall consider whether the protective measures can be maintained in the condition necessary to provide the required level of protection.</p>	✓	PASS

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