Document No. OTR/MCSG/ Machines for Rubber and Plastics/1/July 2025

MACHINE CATEGORY SPECIFIC GUIDELINES FOR

GRANT OF BIS CERTIFICATION AS PER "THE MACHINERY AND ELECTRICAL EQUIPMENT SAFETY (OMNIBUS TECHNICAL REGULATIONS) ORDER , 2024" UNDER SCHEME-X OF BUREAU OF INDIAN STANDARDS (CONFORMITY ASSESSMENT) REGULATIONS, 2018 – GUIDELINES FOR MACHINERY FOR WORKING RUBBER AND PLASTICS

These Machine category specific Guidelines shall be used as reference document by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-X of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products notified under "The Machinery and Electrical Equipment Safety (Omnibus Technical Regulations) Order , 2024". The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.

Section of the Guidelines	Aspects dealt with
A.	Introduction
B.	Machine Category specific requirements to be submitted in Technical File of the Machines *[This section stipulates the additional Machine category specific requirements to be submitted in Technical File of the Machines, other than those specified in the General Guidelines for grant of licence]*
C.	Series/Grouping guidelines for Grant of licence/Change in Scope of licence
D.	Labelling and Marking requirements
E.	Scope of Licence
F.	Scope of Certificate of Conformity (CoC)

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CENTRAL MARKS DEPARTMENT-III

Our ref: CMD-III/OTR/ Machinery for working Rubber and Plastics 22 July 2025

Subject: Machine Category Specific Guidelines for grant of BIS Certification as per "The Machinery and Electrical Equipment Safety (Omnibus Technical Regulations) Order , 2024" under Scheme-X of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 – Guidelines for "Machinery for working Rubber and Plastics"

This document stipulates the Machine category Specific Guidelines for Grant of Licence (GoL)/change in Scope of Licence (CSoL)/Grant of Certificate of Conformity, and are to be read in conjunction with BIS Act 2016 and Rules, Regulations framed thereunder. These guidelines are also to be read in conjunction with the general guidelines for grant of BIS Certification issued vide CMD-I/ 2:17:1 (OTR) dated 11 July 2025, as modified/revised from time to time. Any situation, in general, not covered in these guidelines is to be dealt with as per the provisions of BIS Act, Rules and Regulations by the Regional Offices (ROs) and Branch Offices (BOs).

SECTION A: Introduction

1. These Machine category Specific Guidelines shall be used for the purpose of grant of licence/change in scope of licence for "Machinery for working Rubber and Plastics" specified at Sl. No. 12 of the Third Schedule of the "The Machinery and Electrical Equipment Safety (Omnibus Technical Regulations) Order , 2024" and subsequent amendments made from time to time.

2. For the purpose of obtaining the licence/change in scope of licence from the Bureau, Manufacturer shall apply to Bureau of Indian Standards after ascertaining the scope of licence along with technical file including compliance report(s) as per the procedure defined by the Bureau of Indian Standards under the Conformity Assessment Scheme as specified in "The Machinery and Electrical Equipment Safety (Omnibus Technical Regulations) Order , 2024" and subsequent amendments made from time to time ensuring the required number of sample(s) in respect of a product series/ range or group, as stipulated further in these Guidelines.

3. For the purpose of obtaining Certificate of Conformity (CoC) in respect of a Machine which is not intended to be manufactured on a continuous basis, from the Bureau, Manufacturer shall apply to Bureau of Indian Standards ascertaining the scope of CoC and technical file including compliance report(s), as per the procedure defined by the Bureau of Indian Standards under the Conformity Assessment Scheme as specified in "The Machinery and Electrical Equipment Safety (Omnibus Technical Regulations) Order , 2024" and subsequent amendments made from time to time. One CoC will be granted for Machines of the same Type (Injection Moulding Machine, Extruder, Blow Moulding Machine etc.) only. The scope of CoC shall be limited to the Batch Number/Serial Nos of the Machine only and the same shall be clearly specified in the scope of CoC granted.

SECTION B. Machine specific requirements to be submitted in Technical File of the Machines:

a) General

1. Compliance to the Indian standards and Essential requirements to be submitted in the Technical file of the Machine:

i. As per the provisions of "The Machinery and Electrical Equipment Safety (Omnibus Technical Regulations) Order , 2024 (OTR)", Each machine, or as the case may be, electrical equipment specified in the first Schedule shall conform to the corresponding Indian Standards, as applicable, as given below:-
   a) Type A standards as given below: IS 16819:2018/ISO 12100:2010 (Safety of Machinery General Principles for Design- Risk Assessment and Risk Reduction and,
   b) Type B Standards –as per the second schedule of the Order;
   c) Type C Standards – as per the third Schedule of the Order:

   Provided that if a Type C standard deviates from one or more technical provisions dealt with by Type A or Type B standard, Type C standard takes precedence.

ii. For each model of the machine Applicant manufacturer shall identify the applicable Indian standard and essential requirements, and submit the same in the technical file of the machine along with the application for grant of BIS Certification.

iii. For machines, of which Type C Standard are already mapped in the Third Schedule of the OTR, compliance shall necessarily include that Standard/Essential requirement.

iv. For Machines, against which there is no Type C Standard has been mapped as of now, compliance shall necessarily include Type A Standard and Type B Standards (as identified by the manufacturer and as applicable to the machine). In such cases, Manufacturer may himself identify any one or more or Part of Type C Indian Standards available, which he thinks is/are applicable to the particular machine from the point of view of its safety. Manufacturer may submit the compliance to these standards also. In such case, compliance may be checked against these identified Standard(s) or requirements, as applicable, by BIS.

v. Indian standards and Essential requirements, as applicable, to which the Machine conform shall be specified in the Scope of licence or CoC.

2. Submission of technical file:

i) Technical file shall be submitted for each type of Machine (*Injection Moulding Machine, Extruder, Blow Moulding Machine etc.*) **and for each model** of the Machine, separately.

ii) However, for any Machine type, **in case the manufacturer feels that there are number of models covered in a series, (s)he may submit a combined technical file based on the lead model mentioning details of all models covered in the series with technical justification.** Technical file of lead model of each of the family of models shall be submitted. In the technical file of the lead model, model names/numbers, which are covered in the family shall be specified. *(Please see Section C of these Guidelines regarding family of models)*

b) Suggestive checklists for evaluation of conformity to applicable Indian Standards and Risk Assessment Sheet and their verification, for various types of Machines/Equipment:

1. **For Machines, of which Type C Standard are already mapped in the Third Schedule of the OTR**: In order to help manufacturers preparing the technical file for different types of machines, suggestive checklists for evaluation of conformity to applicable Indian Standards and Risk Assessment Sheet have been prepared by BIS based on the information contained in the respective Type C Standard. These checklists do not contain the exhaustive list and are for the purpose of guidance only. Any other hazards/Risks not listed in these checklists, which may be identified by the manufacturer shall also be listed and adequate safety measures shall be taken and indicated in the above check-list by the manufacturer while submitting the technical file of the Machine.
    i. **Checklist for Injection Moulding Machines** based on IS/ISO 20430 is given at ***Annexure-1***

    Verification of conformity with the safety requirements and/or protective measures shall be done in accordance with Table 1 of IS IS/ISO 20430, as applicable. These protective measures taken by the manufacturer shall be submitted to BIS. These measures may also be verified by BIS during factory visit.
2. **For Machines, against which there is no Type C Standard has been mapped as of now in the OTR**: In order to help manufacturers preparing the technical file for different types of machines, suggestive checklists for evaluation of conformity to applicable Indian Standards and Risk Assessment Sheet have been prepared by BIS for compliance to Type A and Type B Standards. These checklists do not contain the exhaustive list and are for the purpose of guidance only. Any other hazards/Risks not listed in these checklists, which may be identified by the manufacturer shall also be listed and adequate safety measures shall be taken and indicated in the above check-list by the manufacturer while submitting the technical file of the Machine.
    i. **Checklist for Machines** based on IS 16819/ISO 12100 is given at ***Annexure-2***
    ii. **Checklist for Machines** based on IS 16504-1/IEC 60204-1 is given at ***Annexure-3.***

c) Compliance of the Safety related Parts of Control System (SRP/CS) for various Machines as specified in respective Type C Indian standard to be submitted in the Technical file of the Machine:

1. For Machines, of which Type C Standard are already mapped in the Third Schedule of the OTR:

i. **For Injection Moulding Machines**: Protective systems and safety-related parts of the control systems shall be in accordance with:
-Protective Type I, II and III as specified in Annexes B, C and D of IS/ISO 20430. These annexes describe minimum requirements and the calculation of the PL of the whole system achieved is not required; or

- The PLr in accordance with ISO 13849-1:2015, as specified in the relevant subclauses.
NOTE: The safety level achieved when applying the PLr as specified in the relevant subclauses is at least equivalent to the safety level achieved when applying the annexes.

2. Machines of which there is no Type C Standard specified in the OTR, Safety-related components implementing the safety functions shall meet the requirements for the performance level and category as required as per Risk assessment done**.**

SECTION C. Series/Grouping guidelines for Grant of licence/Change in Scope of licence:

a) General:

1. Manufacturer shall declare all the models of each type of the Machine (*Injection Moulding Machine, Extruder, Blow Moulding Machine etc.*) intended to be covered in the Licence.
2. For CoC, Manufacturer shall declare Type of Machine intended to be covered in the scope of CoC. Further, Date/Month of manufacturing, Model name/number and Lot No./Batch Number along with Serial Nos. of the Machine, shall also be declared for unique identification of Machines covered in the scope of CoC.
3. **Manufacturer shall ensure that each model of the Machine conforms to the Indian standard or Essential requirements, as applicable**. However, for the purpose of demonstration of the compliance to applicable Indian Standards or the essential requirements, manufacturer may submit the Risk assessment and compliance reports of the representative model (Lead model) only as described below at sub-para (*b)*:

b) Family of models and Lead model in a family:

1. The manufacturer shall declare all the models (by name/ number/ code, as uniquely defined by the manufacturer) of the machine of each type (viz. Injection Moulding Machine, Extruder, Blow Moulding Machine etc.)
2. The manufacturer shall identify and declare **Family of models** and the **lead model** in each family of models. **Lead model** represents a family of models declared by manufacturer. **While declaring a family of models, similarity of risks including Type of Hazards which are associated with the members of the family of machines shall be considered. Model posing highest risk and hence employing the maximum safety features shall be declared as the lead model of the family**.
3. For the purpose of demonstration of the compliance to applicable Indian Standards or the essential requirements, manufacturer shall submit compliance of the lead model. Technical file containing Risk assessment and compliance of this lead model shall be submitted along with application.
4. Based on the justification submitted by the manufacturer and subsequent desk-assessment and factory assessment, BIS may agree/modify/not agree to such groupings.

5. Coverage of varieties of Machines in the scope of Machines shall be determined accordingly by BIS.
6. During operation of the licence if any new model is intended to be covered within the existing scope of licence and which are considered to be in the same family already covered, application for inclusion of all such new models (Change in scope of licence) in scope of licence along with necessary fee and technical file shall be submitted by licensee to BIS. Based on the assessment made, new models may be included in the scope of licence after review of technical file and/or factory visit. Provision of family of models and submission of technical file of the lead model, as above, may be applicable for such inclusions.

SECTION D. Labelling and Marking requirements:

a) Each machine or equipment, shall conform to the labeling and marking requirements as specified in the Scheme X of the BIS (Conformity Assessment) Regulations, 2018 and also to be complied with the safety instructions or symbols, if any required to be labeled or marked on the machinery or electrical equipment, as the case may be.

b) Each machine or equipment, shall also conform to the labeling and marking requirements including information for use, as specified in the respective Indian Standards i.e. to IS/ISO 20430 for Injection Moulding Machine**. Machines for which there is no Type C Standard specified in the OTR, labelling and Marking requirements shall conform to IS 16819/ISO 12100 and other applicable Type B Standards.**

c) Information to be given as above shall be given at least in English language.

d) The BIS Standard Mark, as given in the Schedule of the licence, shall be marked on each machine, provided always that the product thus marked conforms to the corresponding Indian standard or Essential requirements, as applicable.

SECTION E. SCOPE OF LICENCE:

Licence is granted to use Standard Mark with following scope:

Product	**Scope of licence**	**Standard Mark**
Machinery for working Rubber and Plastics	Please see Annexure attached	IS 16819:2018/ISO 12100:2010  CM/L- XXXXXXXXXX

Annexure to the scope of licence Number……..

Type of Machine/Equipment *(Injection Moulding Machine, Extruder, Blow Moulding Machine etc.)*	Models covered		Conforming to Indian Standard(s) or Essential requirements
	Model number/name as uniquely identified, of the lead model in the family	Model number/name as uniquely identified, of the machines covered in the family	

Illustrative example 1 of Annexure to scope of licence (applicable for scope covering electro-discharge machine and Milling Machine):

Type of Machine/Equipment *(Injection Moulding Machine, Extruder, Blow Moulding Machine etc.)*	Models covered		Conforming to Indian Standard(s) or Essential requirements
	Model number/name as uniquely identified, of the lead model in the family	Model number/name as uniquely identified, of the machines covered in the family	
Injection Moulding Machine	LM-IMM-1	IMM-1-1	IS 16819: 2018/ISO 12100: 2010 IS/ISO 20430: 2020
		IMM-1-2	
		IMM-1-3	
Injection Moulding Machine	LM-IMM-1	IMM-2-1	IS 16819: 2018/ISO 12100: 2010 IS/ISO 20430: 2020
		IMM-2-2	
		IMM-2-2	
Blow Moulding Machine	LM-BMM-1	BMM-1-1	IS 16819: 2018/ISO 12100: 2010
		BMM-1-2	
		BMM-1-3	

SECTION F. SCOPE OF CERTIFICATE OF CONFORMITY (CoC):

Certificate of Conformity is granted with following scope:

Product	Scope of licence
Machinery for working Rubber and Plastics	Please see Annexure attached

Annexure to the scope of Certificate of Conformity number ……..

Type of Machine/Equipment *(Either Injection Moulding Machine, Extruder, Blow Moulding Machine etc.)*	Models covered		Conforming to Indian Standard(s) or Essential requirements	Lot No./ Batch no. with serial numbers of the Machine (from…to…)	Total number of Machine/Equipment	Date/month of manufacturing of the Machine
	Model number/name as uniquely identified, of the lead model in the family	Model number/name as uniquely identified, of the machines covered in the family				

Illustrative example 1 for CoC:

Type of Machine/Equipment *(Either Injection Moulding Machine, Extruder, Blow Moulding Machine etc.)*	Models covered		Conforming to Indian Standard(s) or Essential requirements	Lot No./ Batch no. with serial numbers of the Machine (from…to…)	Total number of Machine/Equipment	Date/month of manufacturing of the Machine
	Model number/name as uniquely identified, of the lead model in the family	Model number/name as uniquely identified, of the machines covered in the family				
Injection Moulding Machine	LM-IMM-1	IMM-1-1	IS 16819: 2018/ISO 12100: 2010 IS/ISO 20430: 2020	Batch no.- IMM 01 Serial No. 001 to 200	200	January 2025 to March 2025
Injection Moulding Machine	LM-IMM-1	IMM-1-2	IS 16819: 2018/ISO 12100: 2010 IS/ISO 20430: 2020	Batch no.- IMM 02 Serial No. 201 to 300	100	January 2025 to March 2025

Illustrative example 2 for CoC:

Type of Machine/Equipment *(Either Injection Moulding Machine, Extruder, Blow Moulding Machine etc.)*	Models covered		Conforming to Indian Standard(s) or Essential requirements	Lot No./ Batch no. with serial numbers of the Machine (from…to…)	Total number of Machine/Equipment	Date/month of manufacturing of the Machine
	Model number/name as uniquely identified, of the lead model in the family	Model number/name as uniquely identified, of the machines covered in the family				
Blow Moulding Machine	LM-BMM-1	BMM-1-1	IS 16819: 2018/ISO 12100: 2010	Batch no.- BMM 01 Serial No. 001 to 200	200	January 2025 to March 2025
Blow Moulding Machine	LM-BMM-1	BMM-1-2	IS 16819: 2018/ISO 12100: 2010	Batch no.- EDM 02 Serial No. 201 to 300	100	January 2025 to March 2025

Annexure- 1

Suggestive Check list for evaluation of conformity to applicable Indian Standards and Risk Assessment Sheet- Injection Moulding Machines (*For guidance*)

Risk Analysis							**Risk mitigation**					**Reference documents for complaince**	**Risk evaluation**
Hazard identification			Risk Estimation (Using any Tool such as Risk Matrix (or) Risk Graph (or) Numerical Scoring (or) Combination of Tools as per IS/ISO/TR/ 14121-2)										
Area-wise Hazards	Element / Source of hazard		Harm	Severity	Probability of occurrence of harm	Risk level/Index/Score	Relevant subclause of identified type-C Standard IS/ISO 20430: 2020	Measures taken to eliminate (or) reduce risk			Risk level/Index/ Score after Risk Mitigation measures taken	Technical Documentation / Compliance report (*may contain report of visual inspection or testing or documentation analysis*)	Has the risk been adequetly reduced (Yes/No)
	Hazards, hazardous situations and hazardous events	Potential consequences						Safety by Design	Safety through additional measures (eg, guard, interlocks, CBs etc)	Safety through any other measures (including warning signs, Information for Use, etc)			
1	**Hazards in Mould area:**												
		Closing movement of the platen, including movement due to gravity on downstroking machines	Crushing, shearing, and/ or impact				4.2.1, 4.2.2, 4.2.6, 4.2.7, 6.2.9, 6.2.11						
		Closing movement of the platen for mould height adjustment	Crushing, shearing, and/ or impact				4.2.3.1						

		Closing movement of the movable platen with a mould attached to it during mould setting when the mould area is accessible through the opening for the nozzle in the fixed platen	Crushing, shearing, and/ or impact					4.2.1, 4.2.2, 4.2.6, 4.2.7						
		Movement of the nozzle tip of the injection unit through the opening for the nozzle in the fixed platen	Crushing, shearing, and/ or impact					4.2.3.1, 4.5, 4.6						
		Movement of the nozzle tip of any additional injection unit when it comes into contact with the mould	Crushing, shearing, and/ or impact					4.2.3.1, 4.5, 4.6						
		Movement of cores and ejectors and their drive mechanisms	Crushing, shearing, and/ or impact					4.2.3.1, 4.2.3.2, 4.2.7, 4.3.2, 4.4, 6.2.7						
		Tie-bar movement	Crushing, shearing, and/ or impact					4.1, 4.2						
		Actions of multi-mould linkages if they are integral parts of the machine	Crushing, shearing, and/ or impact					4.1, 4.2						

		Mould area hazards related to mechanical parts (e.g. inserts) projected from the mould area due to mould closing movement	Crushing, shearing, and/ or impact					4.2						
		Movement of other mechanical device(s)	Crushing, shearing, and/ or impact					4.1, 4.2, 4.3, 4.5, 4.6, 4.7						
		Movement of device below and associated with rotary or shuttle table	Crushing, shearing, and/ or impact					4.9						
		Over-pressurization in the nozzle	Crushing, shearing, and/ or impact					4.5						
		Hazards related to exposed and unprotected heater or nozzle mounted sensors	Burns or scalds					4.2.5						
		Splashing of material from the mould and/or the nozzle	Damage to eyes and skin, burns or scalds					4.2, 4.5						
		Operating temperatures of the moulds	Burns or scalds					4.2.5, 6.2.10, 6.2.14						

		Operating temperatures of heating elements of the moulds and/or nozzle and/or injection barrels	Burns or scalds					4.2.5, 6.2.10, 6.2.14						
		Operating temperatures of material released from the mould and/or nozzle	Burns or scalds					4.2.5, 6.2.10, 6.2.14						
2	**Hazards in the clamping mechanism area or area behind the movable platen:**													
		Movements of the drive and clamping mechanisms of the platen	Crushing, shearing, and/ or impact					4.3						
		Opening movement of the platen	Crushing, shearing, and/ or impact					4.3						
		Movements of core and ejector drive mechanisms	Crushing, shearing, and/ or impact					4.2.3.1, 4.2.3.2, 4.2.7,						
		Opening movement of the platen due to gravity on upstroking machines	Crushing, shearing, and/ or impact					4.3.2, 4.4, 6.2.7						
		Unexpected movement of the movable platen due to stored energy in the toggle system	Crushing, shearing, and/ or impact					4.3.2						

		Opening movement of power-operated guards for the mould area	Crushing, shearing, and/ or impact					4.3.3, 6.2.8						
3	**Hazards in the area of movement of core and ejector and their drive mechanisms outside both the mould area and the clamping mechanism area:**													
		Movements of core and ejector and their drive mechanisms outside the mould area	Crushing, shearing, and/ or impact					4.2.3.2, 4.4, 6.2.7						
		Movements of core and ejector and their drive mechanisms outside the clamping mechanism area	Crushing, shearing, and/ or impact					4.2.3.2, 4.4, 6.2.7						
4	**Hazards in the nozzle area:**													
		Forward movement of the injection unit(s)	Crushing and/or shearing					4.5						
		Movements of parts of the power-operated shut-off nozzle and its drive	Crushing and/or shearing					4.5						
		Movement of the exposed plasticizing screw dur- ing changing of the plasticizing screw	Impact and/or entanglement					4.5, 6.2.18						
		Splashing of material from the nozzle(s)	Damage to eyes and skin, burns or scalds					4.5						

		Incorrect mounting of the nozzle	Impact					4.5, 6.2.14, 6.2.18						
		Use of an incorrect type of nozzle	Impact					4.5, 6.2.14, 6.2.18						
		Operating temperatures of the nozzle(s)	Burns or scalds					4.5						
		Operating temperatures of plasticized material released from the nozzle(s)	Burns or scalds					4.5						
5	**Hazards in the injection unit area:**													
		Unintentional movement due to gravity of vertical or inclined injection units	Crushing, shearing and/ or drawing-in					4.1.9, 4.2, 4.6						
		Movement of the plasticizing screw and/or the injection piston in the plasticizing and/or injection barrel, accessible through the feed opening	Crushing, shearing and/ or drawing-in					4.6						
		Movement of the hopper attached to the injection unit towards the fixed platen (especially in the case of small machines)	Crushing, shearing and/ or drawing-in					4.6						
		Movement of the injection mechanism	Crushing, shearing and/ or drawing-in					4.6						

		Movement of the plasticizing mechanism	Crushing, shearing and/ or drawing-in					4.6						
		Operating temperatures of the injection unit	Burns or scalds					4.5.2, 4.6.2						
		Operating temperatures of the heating elements	Burns or scalds					4.5.2, 4.6.2						
		e.g. heater bands, heat exchangers	Burns or scalds					4.5.2, 4.6.2						
		Operating temperatures of the plasticized material released from the vent opening	Burns or scalds					4.5.2, 4.6.2						
		Operating temperatures of hot gas or material ejected through the feed opening following a deg- radation of the material due to excessive tempera- ture and/or residence time in the barrel	Impact, burns or scalds due to escape/leakage/s plashing of material					4.6.3						
6	**Hazards in the discharge area:**													
		Moving parts accessible through the discharge aperture	Crushing, shearing and/ or impact					4.7						

		Operating temperature of the mould	Burns and/or scalds					4.7, 4.2.5						
		Operating temperature of heating elements of the mould	Burns and/or scalds					4.7, 4.2.5						
		Operating temperature of plasticized material released from/through the mould	Burns and/or scalds					4.7, 4.2.5						
7	**Hazards not associated with a particular area of the machine:**													
		Tearing or detachment of flexible hoses with pres- sures higher than 5 MPa (725 psig) for hydraulics and higher than 1 MPa (145 psig) for pneumatic from their connection points	Crushing, shearing, whiplash and/or impact					4.8.1						

		Unintended release of fluids under pressure from hydraulic, pneumatic, or heat conditioning sys-tems, in particular from flexible hoses and their connection points with pressures higher than 5 MPa (725 psig) for hydraulics and higher than 1 MPa (145 psig)	Damage to the eyes or skin					4.8.2						
		Use of unsuitable tools or equipment during adjustment and maintenance	Injury					4.8.3, 6.2.18						
		Release of stored or residual energy during adjustment and maintenance	Crushing, shearing and/ or impact					4.8.3, 6.2.18						
		Direct or indirect contact with live conductive electrical parts	Electric shock and/or burns					4.8.4						
		Arc flash hazards	Impact, electrocution, burn and/ or shock					4.8.4						

		Malfunction of the control circuits due to elec-tromagnetic interference with the electrical equipment	Unintentional movements resulting in injuries					4.8.4						
		Operating temperatures of heat conditioning sys-tem hoses and fittings	Burns and/or scalds					4.8.5						
		Operating temperatures of fluids released from the heat conditioning system	Burns and/or scalds					4.8.5						
		Noise	Permanent hearing loss, tinnitus, fatigue, stress, loss of balance, loss of awareness					4.8.6, 6.2.24						
		Noise	Accidents caused by interference with speech communication or auditory signals					4.8.6, 6.2.24						
		Contact with or inhalation of gases, fumes, mist or dust harmful to health during plasticizing of the material and subsequent injection into the mould or purging	Damage to eyes and skin, poison-ing, headache, discomfort and/or breathing difficulties					4.8.7, 6.2.19						

		Contact with or inhalation of gases, fumes, mist or dust harmful to health during curing or vulcanis- ing of the part in the mould	Damage to eyes and skin, poison- ing, headache, discomfort and/or breathing difficulties					4.8.7, 6.2.19						
		Contact with or inhalation of gases, fumes, mist or dust harmful to health when the mould is not closed	Damage to eyes and skin, poison- ing, headache, discomfort and/or breathing difficulties					4.8.7, 6.2.19						
		Lack of oxygen when nitrogen is used	Breathing difficulties and/or suffocation					4.8.7, 6.2.19						
		Slips, trips and falls from designated access or designated working positions on or around the machine	Slipping, tripping and/or falling					4.8.8, 6.2.20, 6.2.21						
		Malfunctions of the hydraulic and pneumatic sys- tems including cylinders and other actuator devices	Unintentional movements resulting in injuries					4.8.9, 6.2.23						
		Movement of power-operated guards	Crushing, shearing and/ or impact					4.8.10						

		Interrupted forward movement of the screw/pis- ton resulting in sprue remaining in the mould	Burns and/or scalds due to splashing of material					4.8.11, 6.2.16						
		Interrupted forward movement of the screw/ piston resulting in the accumulation of dangerous pressure in the injection barrel	Burns and/or scalds due to splashing of material					4.8.11, 6.2.16						
8	**Hazards associated with specific machine design:**													
	Carousel machines:													
		Movement of the carousel itself	Impact and entanglement					4.9.1						
		Movement of the carousel in the areas between the moving carousel and fixed parts	Crushing, shearing and/ or drawing-in					4.9.1						
	Shuttle-table machines/machines with sliding table/platen and/or turn-table machines:													
		Functional or unintentional movement of the table or sliding platen	Crushing, shearing, impact, and/ or drawing-in					4.9.1						
		Unintentional gravity descent of the shuttle-table	Crushing, shearing and/ or impact					4.9.1						
	Multi-station machines with mobile injection unit:													

		Movement of the mobile injection unit between the clamping units	Crushing, shearing and/ or impact					4.9.2						
	Cellular foam injection moulding machines:													
		Uncontrolled escape of the melt from the nozzle or the mould	Damage to eyes and skin, burn and/or scalds					4.9.3, 6.2.22						
	Machines where the injection unit discharges towards the operating position:													
		Ejection of material directly to the operating position (see 3.1.23 of IS/ISO 20430) as a result of the forward movement of the plasticizing screw or piston, or degradation of the material	Damage to eyes and skin, burn and/or scalds					4.9.4, 6.2.15						

Note: This is not an exhaustive list, any other hazards not listed above, which may be identified by the manufacturer shall also be listed and adequate safety measures shall be taken and indicated in the above check-list by the manufacturer while submitting the technical file of the Machine

Annexure- 2

Suggestive Check list for evaluation of conformity to applicable Indian Standards and Risk Assessment Sheet- (*Machine name*) (*For guidance*)

	Risk Analysis						**Risk mitigation**						**Reference documents for complaince**	**Risk evaluation**
	Hazard identification			Risk Estimation (Using any Tool such as Risk Matrix (or) Risk Graph (or) Numerical Scoring (or) Combination of Tools as per IS/ISO/TR/ 14121-2)						Measures taken to eliminate (or) reduce risk					
	Type of Hazard	Element / Source of hazard (Please refer to Annex B of IS 16819/ ISO 12100)		Harm	Severity	Probability of occurrence of harm	Risk level/Index/Score	Relevant subclause of IS 16819/ ISO 12100	Relevant subclause of identified type-C Standard IS XXXX, if identified (Optional)	Safety by Design	Safety through additional measures (eg, guard, interlocks, CBs etc)	Safety through any other measures (including warning signs, Information for Use, etc)	Risk level/Index/ Score after Risk Mitigation measures taken	Technical Documentation / Compliance report	Has the risk been adequetly reduced (Y/N)
		Origin[a]	Potential consequences[b]												
1	**Mechanical hazards:**	□ acceleration, deceleration; □ angular parts; □ approach of a moving element to a fixed part; □ cutting parts; □ elastic elements; □ falling objects; □ gravity; □ height from the ground; □ high pressure; □ instability; □ kinetic energy; □ machinery mobility; □ moving elements; □ rotating elements; □ rough, slippery surface;	□ being run over; □ being thrown; □ crushing; □ cutting or severing; □ drawing-in or trapping; □ entanglement; □ friction or abrasion; □ impact; □ injection; □ shearing; □ slipping, tripping and falling; □ stabbing or puncture; □ suffocation.												

2	**Electrical Hazards:**	□ arc; □ electromagnetic phenomena; □ electrostatic phenomena; □ live parts; □ not enough distance to live parts under high voltage; □ overload; □ parts which have become live under fault conditions; □ short-circuit; □ thermal radiation	□ burn; □ chemical effects; □ effects on medical implants; □ electrocution; □ falling, being thrown; □ fire; □ projection of molten particles; □ shock.												
3	**Thermal Hazards**	□ explosion; □ flame; □ objects or materials with a high or low temperature; □ radiation from heat sources.	□ burn; □ dehydration; □ discomfort; □ frostbite; □ injuries by the radiation of heat sources; □ scald.												
4	**Noise Hazards:**	□ cavitation phenomena; □ exhausting system; □ gas leaking at high speed; □ manufacturing process (stamping, cutting, etc.); □ moving parts; □ scraping surfaces; □ unbalanced rotating parts; □ whistling pneumatics; □ worn parts.	□ discomfort; □ loss of awareness; □ loss of balance; □ permanent hearing loss; □ stress; □ tinnitus; □ tiredness; □ any other (for example, mechanical, electrical) as a consequence of an interference with speech communication or with acoustic signals.												

5	**Vibration hazards:**	□ cavitation phenomena; □ misalignment of moving parts; □ mobile equipment; □ scraping surfaces; □ unbalanced rotating parts; □ vibrating equipment; □ worn parts.	□ discomfort; □ low-back morbidity; □ neurological disorder; □ osteo-articular disorder; □ trauma of the spine; □ vascular disorder												
5	**Vibration hazards (not relevant to EDM):**														
6	**Radiation Hazards:**	□ ionizing radiation source; □ low frequency electromagnetic radiation; □ optical radiation (infrared, visible and ultraviolet), including laser; □ radio frequency electromagnetic radiation.	□ burn; □ damage to eyes and skin; □ effects on reproductive capability; □ mutation; □ headache, insomnia, etc.												
7	**Material/ Substance Hazards:**	□ aerosol; □ biological and microbiological (viral or bacterial) agent; □ combustible; □ dust; □ explosive; □ fibre; □ flammable; □ fluid; □ fume; □ gas; □ mist; □ oxidizer.	□ breathing difficulties, suffocation; □ cancer; □ corrosion; □ effects on reproductive capability; □ explosion; □ fire; □ infection; □ mutation; □ poisoning; □ sensitization.												

8	**Ergonomic Hazards:**	□ access; □ design or location of indicators and visual displays units; □ design, location or identification of control devices; □ effort; □ flicker, dazzling, shadow, stroboscopic effect; □ local lighting; □ mental overload/underload; □ posture; □ repetitive activity; □ visibility.	□ discomfort; □ fatigue; □ musculoskeletal disorder; □ stress; □ any other (for example, mechanical, electrical) as a consequence of a human error.												
9	**Hazards associated with the environment in which the machine is used:**	□ dust and fog; □ electromagnetic disturbance; □ lightning; □ moisture; □ pollution; □ snow; □ temperature; □ water; □ wind; □ lack of oxygen.	□ burn; □ slight disease; □ slipping, falling; □ suffocation; □ any other as a consequence of the effect caused by the sources of the hazards on the machine or parts of the machine.												
10	**Combination of Hazards:**	□ for example, repetitive activity + effort + high environmental temperature	□ for example, dehydration, loss of awareness, heat stroke												

Note: This is not an exhaustive list, any other hazards not listed above, which may be identified by the manufacturer shall also be listed and adequate safety measures shall be taken and indicated in the above check-list by the manufacturer while submitting the technical file of the Machine. a. Origin: A single origin of a hazard can have several potential consequences.

b. Potential consequences: For each type of hazard or group of hazards, some potential consequences can be related to several origins of hazard

Annexure- 3

Suggestive Check list for evaluation of conformity to Type B Standard - IS 16504-1/IEC 60204-1 for General requirements (*For guidance*)

Clause of IEC 60204-1	Specified requirements	Whether requirement is applicable to the Machine or not applicable	Conformity (Yes/No)	Technical documentation submitted as evidence of conformity (Design document/Risk assement/ Safety function diagrams/safety validation reports/Test report/supplier test certificate etc.)
4	General Requirements			
4.1	Whether information as per Annexure B of IEC 60204-1 : 2016 is provided by the manufacturer?			
4.2	Selection of equipment			
4.2.1	Components and devices			
4.2.2	Switchgear: Compliance to IEC 61439			
4.3	Electrical supply: Whether equipment deisgned as per prscribed Electrical supply conditions?			
4.3.2	AC Supply			
4.3.3	DC Supply			
4.3.4	Whether can be categorized as special supply system?			
4.4	Physical Environment and Operating Conditions			
5	Incoming supply conductor terminations and devices for disconnecting and switching off			
5.1	Incoming supply conductor terminations			
	Identification of terminals for incoming supply connection			
5.2	Terminal for connection of the external protective conductor			
5.3	Whether supply disconneting (isolating) device provided?			
	Whether provided for each incoming supply?			
	Whether provided for each on-board power supply?			
5.3.2	Type of supply disconneting device			
5.3.3	Requirements			
5.3.4	Operating means of the supply disconnecting device			
5.3.5	Excepted circuits			
5.4	Devices for removal of power for prevention of unexpected start-up			
5.5	Devices for isolating electrical equipment			
5.6	Protection against unauthorized, inadvertent and/or mistaken connection			
6	Protection against electric shock			
6.2.2	Whether protection by enclosure?			
6.2.3	Whether protection by insulation?			
6.2.4	Whether protection against residual voltage required?			
6.2.5	Protection by barrier			
6.2.6	Protection by placing out of reach or protection by obstacles			
6.3	Fault protection			
6.3.2	Whether by prevention of occurrence of touch voltage?			
6.3.3	Whether protection by automatic disconnection of supply?			
6.4	Protection by the use of PELV			
7	Protection of equipment			
7.2	Overcurrent protection			
7.3	Protection of motors against overheating			

7.4	Protection against abnormal temperature			
7.5	Protection against the effects of supply interruption or voltage reduction and subsequent restoration			
7.6	Motor overspeed protection			
7.7	Additional earth fault/residual current protection			
7.8	Phase sequence protection			
7.9	Protection against overvoltages due to lightning and to switching surges			
7.10	Short-circuit current rating			
8	Equipotential bonding			
8.2	Protective Bonding Circuit			
8.3	Measures to restrict the effects of high leakage current			
8.4	Functional bonding			
9	Control circuits and control functions			
9.1	Control circuits			
9.1.2	Control circuit voltages			
9.1.3	Protection			
9.2	Control functions			
9.2.2	Categories of stop functions			
9.2.3	Operations			
9.2.3.4	Emergency operations (emergency stop, emergency switching off			
9.2.4	Cableless control system (CCS)			
9.3	Protective interlocks			
9.4	Control functions in the event of failure			
10	Operator interface and machine-mounted control devices			
10.1.2	Location and mounting			
10.1.3	Protection			
10.1.4	Position sensors			
10.1.5	Portable and pendant control stations			
10.2	Actuators			
10.3	Indicator lights and displays			
10.4	Illuminated push-buttons			
10.5	Rotary control devices			
10.6	Start devices			
10.7	Emergency stop devices			
10.8	Emergency switching off devices			
10.9	Enabling control device			
11	Controlgear: location, mounting, and enclosures			
11.2	Location and mounting			
11.3	Degrees of protection			
11.4	Enclosures, doors and openings			
11.5	Access to electrical equipment			
12	Conductors and cables			
12.2	Conductors			
12.3	Insulation			
12.4	Current-carrying capacity in normal service			
12.5	Conductor and cable voltage drop			

12.6	Flexible cable			
12.7	Conductor wires, conductor bars and slip-ring assemblies			
13	Wiring practices			
13.1	Connections and routing			
13.2	Identification of conductors			
13.3	Wiring inside enclosures			
13.4	Wiring outside enclosures			
13.5	Ducts, connection boxes and other boxes			
14	Electric motors and associated equipment			
15	Socket-outlets and lighting			
15.1	Socket-outlets for accessories			
15.2	Local lighting of the machine and of the equipment			
16	Marking, warning signs and reference designations			
17	Technical documentation			
18	Verification			
Annex - B	Enquiry form for the electrical equipment of machines			
Annex - C	Examples of machines covered by this part of IEC 60204			
Annex - F	Guide for the use of this part of IEC 60204			
	Note: This is not an exhaustive list, any other requirements not listed above from IEC 60204-1 or any other Type B Standard, which may be identified by the manufacturer shall also be listed and adequate safety measures shall be taken and indicated in the above check-list by the manufacturer while submitting the technical file of the Machine			