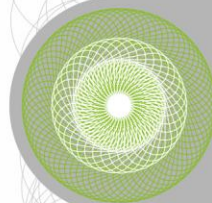




VÝZKUMNÝ  
ÚSTAV  
ŽELEZNIČNÍ, a. s.



## Výzkumný Ústav Železniční, a.s.

Inspection Body No. 4056

Accredited by ČIA according to ČSN EN ISO/IEC 17020:2012



at Novodvorská 1698/138b, Braník, 142 00 Prague 4, Czech Republic

registered as AsBo in ERADIS, EIN number CZ/35/0123/4056

# INSPECTION REPORT

## SAFETY ASSESSMENT REPORT

**Number: 4056/CSM-RA/2024/RST/EN/0301/V01**

**Proposer name:** PREMARK Solutions s.r.o.

**Proposer address:** Hübnerové 925/2, 150 00 Prague 5 - Košíře, Czech Republic

**Designation of change to the railway system:** Railway vehicles parking brake position indicator

**Assessment procedure:** Commission Implementing Regulation (EU) No 402/2013 as amended by (EU) 2015/1136

**Date of Issue:**  
23.05.2024

**Signature:**

**Name:** Ing. Roman Průša

**Title:** Head of the VUZ Inspection Body

Amendment table

Issue	Modification description	Version date
01	Original text	23.05.2024

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## 1 ASSESSMENT TASK

### 1.1 Proposer/Applicant data, assessment subject and description of the contracted work

Proposer name	PREMARK Solutions s.r.o.
Proposer registered office	Hübnerové 925/2, 150 00 Prague 5 - Košíře, Czech Republic
Risk management activities (proposer legal interest)	Manufacturer of subsystem and applicant for assessment
Designation of change to the railway system (system under assessment)	Railway vehicles parking brake position indicator
System definition:	Rolling stock (RST)
Application type (description of negotiated work)	<input checked="" type="checkbox"/> Application for an independent assessment of the correct application of the risk process and the results of that application according to Commission Implementing Regulation (EC) No. 402/2013 of 30.4.2013, art. 6, par. 1 as amended Commission Implementing Regulation (EC) 2015/1136 <input checked="" type="checkbox"/> Application for an assessment of requirements capture pursuant to Commission Implementing Regulation (EU) 2018/545, Article 13

### 1.2 Assessment Body data

Assessment body name	Výzkumný Ústav Železniční, a.s. (Railway Research Institute j.s.c.) Inspection Body No. 4056 (hereinafter assessor)
Assessment body registered office	Novodvorská 1698/138b, Braník, 142 00 Prague 4, Czech Rep.
Competence of assessment body	Certificate of Accreditation No. 555/2023 from 20.10.2023
Name of national accreditation body	Český institut pro akreditaci, o.p.s. (ČIA) (Czech Accreditation Institute)
Registered office of national accreditation body	Olšanská 54/3, Prague 3, PSČ 130 00, Czech Republic
Evidence No. of application at assessor	ZDB24028RST
Record about result of application review	PZB24028RST-0
Appointment of assessment body	Application for Risk Assessment No. ZDB24028RST from 30.04.2024
Contract / order	Sales order no. O2305 004_1 from 13.05.2024, Order confirmation 341 24 0182 from 13.05.2024
Inspection procedure	OS03001I10 Inspection performance PP03002I04 Risk assessment procedure

### 1.3 Overview of normative documents used in assessment

#### 1.3.1 List of European rules and documents

Ser. No.	Reference	Title	Date of issue
1	Directive (EU) 2016/798	on railway safety	11.05.2016
2	Commission Implementing Regulation (EU) No 402/2013	on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 (further CIR CSM-RA)	30.04.2013
3	Commission Implementing Regulation (EU) 2015/1136	amending Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment	13.07.2015
4	Commission Recommendation 2014/897/EU	on matters related to the placing in service and use of structural subsystems and vehicles under Directives 2008/57/EC and 2004/49/EC of the European Parliament and of the Council	05.12.2014
5	Directives (EU) 2016/797	of the European Parliament and of the Council on the interoperability of the rail system within the European Union	11.05.2016
6	Commission Implementing Regulation (EU) 2018/545	establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council	04.04.2018
7	Commission Implementing Regulation (EU) 2019/779	laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 445/2011	16.05.2019
8	ERA/GUI/01-2008/SAF, version 1.1	Guide for the application of the Commission Regulation on the adoption of a common safety method on risk evaluation and assessment as referred to Article 6 (3) (a) of the Railway Safety Directive	06.01.2009
9	ERA/GUI/02-2008/SAF, version 1.1	Collection of examples of risk assessment and of some possible tools supporting the CSM Regulation	06.01.2009
10	ERA 1209/063, version 1.0	Clarification Note on Safe Integration	14.01.2020
11	001NET1108, version 1.1	Recommendation for use Nr 1: Working method of the Assessment Body	13.06.2019

#### 1.3.2 List of notified national safety rules

Ser. No.	Reference	Title	Date of issue
1	Act 266/1994 Sb.	Railway law, as amended	01.01.1995
2	Regulation 100/1995 Sb.	which lays down the requirements for operation, design and manufacturing of specified technical equipment and its concrete expression (Code of specified technical equipment), as amended	18.05.1995
3	Regulation 173/1995 Sb.	Traffic code for railway, as amended	22.06.1995

Ser. No.	Reference	Title	Date of issue
4	Regulation 376/2006 Sb.	about safety system for operating of railway and railway transport and methods at occurrence of outstanding events on railway, as amended	01.08.2006
5	DUCR-59232/18/Kj Railway Authority	Guideline for application of Commission Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009	16.10.2018

Note 1: National rules were used only to assess the significance of the change.

### 1.3.3 Other used documents

Ser. No.	Reference	Title	Date of issue
1	ČSN EN 50126-1 ed. 2	Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Part 1: Generic RAMS Process	03.2019

Harmonized Czech technical standards, which fully adopted the requirements determined by the European standard, were used during the assessment. The normative part of both standards is identical.

### 1.4 Schedule for safety assessment

The assessor has elaborated an internal schedule for assessment PHB24028RST-0 dated 02.05.2024. The internal assessment schedule set out a timetable for the individual evaluation phases and a preliminary deadline for preparation of the safety assessment report by 31.05.2024.

### 1.5 Assessor team data

Name and surname of assessor	Position
Ing. Jan Kopřiva	assessor under supervision for subsystem <i>Railway vehicles</i>
Ing. Jiří Strnisko	leading assessor for subsystem <i>Railway vehicles</i>

### 1.6 Subdeliveries

The undermentioned subdeliveries were used for assessing by the assessor. The necessity of its use resulted from the used rules, consisting in handing over of expert opinions, test results, resp. services used by the assessor as sources for elaborating the Safety assessment report. All submitted subdeliveries have mentioned a conclusion that is possible to accept in the Safety assessment report. Documents of subdeliveries are given in Art. 3.4 of this report.

Ser. No.	Subcontractor name	Registered office	Competence to activity	Subdelivery object
1	None	--	--	--



## 2 ASSESSMENT SCOPE AND ITS LIMITATION

### 2.1 Definition of assessment scope

#### 2.1.1 System definition

The proposer made the assessment of change acc. to CIR CSM-RA, Article 4, as follows:

Change	Assessment of change	Evidence
Possible impact of the change on the safety of railway operation	yes	documents [1] and [2]
Significance of change	significant	
Nature of change	<input checked="" type="checkbox"/> Technical <input type="checkbox"/> Organisational or operational related to maintenance	

The proposer made the minimal definition of the system under assessment acc. to CIR CSM-RA, Annex I, Art. 2.1.2 as follows:

Sub-definition	Subject of system definition	Findings	Evidence
a	System objective (purpose)	Minimalization of risks connected with running with parking brake tightened.	document [2]
b	System functions and elements	Protection of the vehicle against running with parking brake tightened.	document [2]
c	System boundary including other interacting systems	Parking brake mechanism.	document [2]
d	Physical and functional interfaces	Parking brake mechanism.	document [2]
e	System environment	Vehicle.	document [2]
f	Existing safety measures and definition of the safety requirements identified by the risk assessment process	Necessary check of the parking brake position rotating the control wheel.	document [2]
g	Assumptions which shall determine the limits for the risk assessment	Indicator installation.	document [2]

The subject of the independent assessment of the correct application of the risk management process and its results in the sense of CIR CSM-RA is the project of installation of a mechanical parking brake indicator for freight wagons.

The scope of the independent assessment is defined as follows: Mechanical parking brake indicator for freight wagons according to the documents "Užitný vzor číslo 37331: Indikátor stavu ruční brzdy, zejména nákladních železničních vagonů" and "Installation, operation and maintenance instructions for mechanical parking brake indicator for rail freight vehicles". The documents are listed in under No. [3] and [4] given in this report in Art. 3.4.

The process required in CIR CSM-RA was complied.

#### 2.1.2 Project phase

The proposer made the classification of change into system life-cycle acc. to EN 50126-1, Art. 6.2, as follows:

Stage in the system life-cycle	Evidence
2 to 6	document [2]

### 2.1.3 Description of changes under assessment

Brief description of change:

- Mechanical parking brake indicator for freight wagons is a device designed for installation on the parking brake control wheel shaft of the freight wagons. Depending on the control wheel position, the device signals the brake tightening by sliding out a bright red element, which prevents undeliberate running with parking brake tightened.
- The definition of the assessed system according to CIR CSM-RA, Annex I, point 2.1.2, was documented in point 2.1.1 of this report.

The proposer documented the specifications of the change under assessment in documents No. [3] and [4] given in this report in Art. 3.4.

### 2.1.4 Requirements capture

The documentation submitted by the proposer has been assessed for capturing the requirements of the subsystem according to Article 13 of Commission Implementing Regulation (EU) 2018/545. The proposer used the methodology for the risk management process according to CIR CSM-RA, Annex I.

In line with the overall objective to manage the identified risks and mitigate them to an acceptable level, the applicant has implemented before submitting the application, in accordance with Commission Implementing Regulation (EU) 2018/545, Article 13, paragraph 1, capture procedure to ensure that all necessary requirements relating to the vehicle design throughout the lifetime of the vehicle have been:

- properly identified,
- assigned to functions or subsystems or addressed through conditions of use or other constraints; and
- implemented and validated.

The proposer submitted document “Zachycení požadavků (Requirements Capture)” listed under No. [5] in Art. 3.4. Requirements capture according to Article 13, Paragraph 2 of Commission Implementing Regulation (EU) 2018/545 was documented as follows:

Paragraph 2. (a) essential requirements for the subsystem according to Article 3 and Annex III of Directive (EU) 2016/797:

- The proposer has submitted a risk analysis in the document “Risk analysis according to EU regulation 402/2013 for installation and function of mechanical parking brake indicator for rail freight vehicles”, as well as hazard record, technical description and operating and maintenance instructions.
- The documents are listed in under No. [1] to [4] given in this report in Art. 3.4.

Paragraph 2. (b) technical compatibility of the subsystems within the vehicle:

- Irrelevant.

Paragraph 2. (c) safe integration of the subsystems within the vehicle:

- Irrelevant.

Paragraph 2. (d) technical compatibility of the vehicle with the network in the area of use:

- Irrelevant.

According to Commission Implementing Regulation (EU) 2018/545, Article 13, Paragraph 3, the proposer applied the risk management process set out in Annex I to Commission Implementing Regulation (EU) No. 402/2013 as the methodology for requirements capture as regards the essential requirements ‘safety’ related to the vehicle and subsystems as well as safe integration between subsystems for aspects not covered by the TSIs and the national rules.

The methodology used by the proponent to capture requirements according to Article 13 of the Commission Implementing Regulation (EU) 2018/545 and the risk management process used is in accordance with PNK CSM-RA, Annex I.



## 2.2 Limitation of assessment scope

There were not given any granted exceptions in the proposer's application for safety assessment.

## 2.3 Organisation of the project under consideration by the proposer

The proposer chose the following entities for conformity assessment:

Ser. No.	Name of conformity assessment body	Registered office	Competence to activity	Subject of assessment
1	None	--	--	--

## 2.4 Relationship to evaluation activities carried out by other bodies

None.

# 3 DESCRIPTION OF ACTIVITY IN ASSESSMENT

## 3.1 Methods for assessment of compliance

The method applied by assessor was based on CIR CSM-RA, Art. 6, on Guide for the application of this Regulation, on Collection of examples of risk assessment and of some possible tools supporting this Regulation and further on the internal assessor's documentation.

## 3.2 Safety and quality management processes

The proposer PREMARK Solutions s.r.o. implemented and maintains acc. to CIR CSM-RA, Art. 6 an appropriate safety management system for the manufacturing of railway vehicles which includes the processes and methods for risk assessment and implementing of measures for controlling risks relating to design and implementing the change under assessment and delivered following evidences about its implementing:

Safety management system	Evidence
Description of the organisation	--
Description of the safety management process	--
Appointment of expert team to carry out the risk assessment process	Document "Risk analysis according to EU regulation 402/2013 for installation and function of mechanical parking brake indicator for rail freight vehicles" from 08.03.2024
Definition and dividing of tasks for individual actors	PREMARK Solutions s.r.o. Hübnerové 925/2, 150 00 Praha 5 - Košíře, Czech Rep.
Implementation of hazard record	Hazard record
Safety of railway transport operator	Railway transport operator was not defined
Maintenance of the vehicle	Entity in charge of maintenance was not defined
Certificate for safety management system	--

The proposer has implemented and maintains acc. to CIR CSM-RA, Art.6, an appropriate quality management system relating to design and implementing the change under assessment. The proposer's quality management system is not certified, so the proposer has not delivered the evidences about its implementing.

Quality management system	Evidence
Description of the quality management process	--
Certificate of quality management system	--
Certificate of environmental management system	--

The process required in CIR CSM-RA was complied.

### 3.3 Assessment of fulfilling the provisions of CIR CSM-RA, Annex I

#### 3.3.1 Assessment of risk management process

The proposer used appropriately the risk management process acc. to CIR CSM-RA, Art. 6 and Annex I. He documented the single steps in Hazard records. The evidences are given in Art. 3.4 of this report.

The process required in CIR CSM-RA was complied.

#### 3.3.2 Results from assessment of risks identified by proposer

**Hazard** means acc. to CIR CSM-RA, Art. 3 (13) a condition that could lead to an accident.

The proposer identified acc. to CIR CSM-RA, Annex I, Art. 2.1.3 and 2.2.1 all **reasonably foreseeable hazards** for system under assessment incl. its functions and interfaces, incl. subdeliveries as follows:

Ser. No.	Hazard source	Hazard identification	Hazard record No.
1	Parking brake position indication on the freight wagons	Spontaneous moving of the vehicle	PD 23-004-011

The proposer recorded the identified hazard in Hazard record acc. to CIR CSM-RA, Annex I, Art. 2.2.1. The evidences are given in Art. 3.4 of this report.

The process required in CIR CSM-RA was complied.

##### 3.3.2.1 Assessment of risk classification acc. to estimated risk

The proposer made the classification of all identified hazards according to the estimated risk arising from them acc. to CIR CSM-RA, Annex I, Art.2.2.2 as follows:

Ser. No.	Hazard source	Hazard identification	Hazard record No.	Risk classification
1	Parking brake position indication on the freight wagons	Spontaneous moving of the vehicle	PD 23-004-011	Broadly acceptable

The proposer acted at hazard classification acc. to CIR CSM-RA, Art. 4 (1) or (2).

The proposer connected the hazard with broadly acceptable risk acc. to CIR CSM-RA, Annex I, Art.2.2.2.

The proposer acted at identification of broadly acceptable risk in compliance with regulation 173/1995 Coll., § 62, point 2, with Guideline DUCR-59232/18/Kj and with standard ČSN EN 50126.

The proposer recorded the risk classification in Hazard record acc. to CIR CSM-RA, Annex I, Art. 2.2.2. The evidences are given in Art. 3.4 of this report.

The process required in CIR CSM-RA was complied.

##### 3.3.2.2 Assessment of risk acceptance principles for identified hazards

Irrelevant.

##### 3.3.2.2.1 Method of codes of practice

Unused.

##### 3.3.2.2.2 Method of comparison with similar systems

Unused.

##### 3.3.2.2.3 Method of explicit risk estimation

Unused.

##### 3.3.2.2.4 Assessment of specification of safety measures and consecutive safety requirements in relation to the selected risk acceptance principles

Irrelevant.

### 3.3.2.3 Assessment of acceptable risk in comparison to risk acceptance criteria

Irrelevant.

### 3.3.2.4 Assessment of compliance with the safety requirements

The proposer demonstrated the compliance with the safety requirements acc. to CIR CSM-RA, Annex I, Art. 2.1.6 and 3 as follows:

Ser. No.	Hazard source	Hazard identification	Hazard record No.	Demonstration of compliance with safety requirements
1	Parking brake position indication on the freight wagons	Spontaneous moving of the vehicle	PD 23-004-011	Yes, document [4]

The proposer ensured acc. to CIR CSM-RA, Annex I, Art. 1.2.7 that the risk management covers the system itself and the integration in the railway system as a whole. The approach chosen for demonstrating compliance with the safety requirements and the demonstration itself acc. to CIR CSM-RA, Annex I, Art. 3.3 was made by the proposer in an appropriate way.

The evidences of compliance with safety requirements the proposer quoted in Hazard record. The evidences are given in Art. 3.4 of this report.

The process required in CIR CSM-RA was complied.

### 3.4 Evidences from the application of the risk management process – List of assessed documents, delivered evidences and measures and made tests

Ser. No.	Title	Designation	Issuer	Date of issue
[1]	Risk analysis according to EU regulation 402/2013 for installation and function of mechanical parking brake indicator for rail freight vehicles. <i>Analýza rizika dle nařízení EU č. 402/2013 pro instalaci a funkci mechanického indikátoru zajišťovací brzdy pro železniční nákladní vozidla.</i>	PD 23-004-003	PREMARK Solutions s.r.o.	08.03.2024
[2]	Záznam o nebezpečí: Samovolné rozjetí vozidla <i>Hazard record: Spontaneous moving of the vehicle</i>	PD 23-004-011	PREMARK Solutions s.r.o.	02.05.2024
[3]	Užitný vzor číslo 37331: Indikátor stavu ruční brzdy, zejména nákladních železničních vagonů <i>Utility model</i>	CZ 37331 U1	Úřad průmyslového vlastnictví	25.09.2023
[4]	Installation, operation and maintenance instructions for mechanical parking brake indicator for rail freight vehicles. <i>Návod na instalaci, obsluhu a údržbu pro mechanický indikátor zajišťovací brzdy pro železniční nákladní vozidla.</i>	PD 23-004-002	PREMARK Solutions s.r.o.	09.05.2024
[5]	Zachycení požadavků (Requirements Capture)	PD 24-004-052	PREMARK Solutions s.r.o.	16.05.2024

### 3.5 Reports of personal finding - Inspection certificates

The assessor utilized at the assessment the following inspection certificates:

Ser. No.	Title	Designation	Author	Date of issue
1	Inspection protocol	OZB24028RST-0	Ing. Jiří Strnisko	22.05.2024

## 4 FINDING

### 4.1 Requirements capture

Documentation submitted has been assessed in terms of capturing the requirements for the subsystem within the meaning of Article 3 of and Annex III to Directive (EU) 2016/797 according to the Article 13 of Commission Implementing Regulation (EU) 2018/545, including their identification, implementation and validation.

The results of the audits are reviewed in the personal findings of the "Inspection Protocol" report OZB24028RST-0.

Based on the assessment carried out in the previous points of this report, it can be stated that the proposer during the implementation of the significant change:

- Identified all requirements applicable to the design of the vehicle including requirements for safety, reliability and availability, health protection, environmental protection, technical compatibility of subsystems and their safe integration into the vehicle, inspection and accessibility. He integrated these requirements into the technical specification of the vehicle.
- Divided the identified requirements into subsystems in the vehicle architecture.
- Demonstrated correct implementation, verification and validation of all requirements and provided documented evidence of compliance with each step of this development process.

**List of nonconformities and objections:** none

### 4.2 Risk management process

The risk management process used to assess the safety levels and the compliance with safety requirements were documented by the proposer so that the assessment body kept at disposal all necessary evidences demonstrating an appropriate application of risk management process and its result.

It was demonstrated under the supervision of the proposer the fulfilment of the safety requirements resulting from the risk assessment phase. This demonstration of the compliance shall be carried out by the actors responsible for fulfilling the safety requirements, as decided by the proposer. The concerned actors shall declare their agreement with being in charge of fulfilling the safety requirements.

Based on the judgement made in the previous articles of this report it can be stated that the proposer implemented and applied in an appropriate way the safety and quality management processes during design and implementation of the significant change and demonstrated compliance with the safety requirements.

Safety requirements means the safety characteristics (qualitative or quantitative, or when needed both qualitative and quantitative) of a system under assessment and its operation (including operational rules) and maintenance necessary in order to meet legal or company safety targets.

The safety requirements related to the change under assessment are given in Art. 1.3 of this report.

**List of nonconformities and objections:** none

The process required in CIR CSM-RA was complied.

### 4.3 Results of assessments carried out by other conformity assessment bodies or other parties

None.

**List of nonconformities and objections:** none

## 5 CONDITIONS AND LIMITATIONS OF USE

### 5.1 Conditions and limitations for use from the AsBo independent safety assessment

None.

### 5.2 Conditions and restrictions for use transferred through conformity assessment activities of other conformity assessment bodies or other parties

None.

## 6 CONCLUSION

The assessment body carried out the independent assessment of all requirements capture according to Article 13 of Commission Regulation (EU) 2018/545 and change of the railway system with the designation **‘Railway vehicles parking brake position indicator’** from the point of view of appropriateness both in relation to application of risk management process given in CIR CSM-RA, Annex I, and its results.

I state that, on the basis of an independent assessment, the amendment has been shown to comply with all requirements.

The proposer ensured acc. to CIR CSM-RA, Annex I, Art. 1.2.7 that the risk management covers the system itself and the integration in the railway system as a whole.

The process required by CIR CSM-RA has been followed.

**Recommendation of the assessment body:** None

The documentation used for the risk evaluation of the change under assessment shall be kept by the proposer along the whole life-cycle for needs of safety authorities.

The documents utilized for the assessment are stored at the assessor under evidence No. B24028RST.

## 7 ANNEXES

None.

## 8 STATEMENT

The inspection results are related only to the ordered scope of inspection (see the application). The inspection report cannot be reproduced without permission of the inspection body and of the applicant otherwise than as a whole.

ELABORATED BY		
Date of elaboration	Name of leading assessor	Signature
23.05.2024	Ing. Jiří Strnisko	

REVIEWED BY	
Name / Position	Signature
Ing. Jan Veselík / TVS-RST deputy	