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INTERTEK MEDICAL NOTIFIED BODY

OUTLINE OF REQUIREMENTS FOR SUBMISSION OF THE MDR FILE
TECHNICAL GUIDANCE

INTRODUCTION

The Medical Devices Regulation (MDR) 2017/745 requires that the Notified Body undertakes (for products of classification IIA, IIB and III) a review of the Technical Documentation from the manufacturer as either part of the initial certification process, as part of surveillance, recertification and / or as part of significant change notifications.

Annex II of the MDR states the following:-

Technical Documentation

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

As such the format of the file submission and it's contents require to be received in a suitable format for IMNB to review. This document provides clarification in a non consultation manner the expectations from IMNB. This will lead to more efficient reviews, quicker turnaround of the files and consistency of submissions.

It should not be underestimated the extent of the differences in submission of the Technical Documentation between the relevant Medical Device Directive and the MDR and therefore what was previously accepted is no longer possible under the MDR.

Incomplete, incorrect, poorly formatted files and submissions not in the English language cannot be accepted for review by IMNB.

All files are to be in searchable pdf, excl, word documents, native versions are required and not scans of scans. In addition the names of the files must reflect the content of the document. Do not use any password or other security protection on any documents that are submitted.

This outline of documentation is to support a smooth documentation process. It remains the applicant's responsibility to ensure all regulatory requirements are met, and that clear and transparent evidence of conformity to these requirements are provided.

As such the following (as a minimum) is expected to be submitted by each client irrespective of the classification of the product.

File	This is to include the following (as a minimum):
Cover letter	• Headed letter with company name and address, contact details • Introduction to the subject of the letter (type of review, products (including accessories) covered by the review etc...) • Brief overview of the purpose of the file (what is the expected outcome of the review – certification, change approval, other, etc...) • Any specific concerns to be taken into account during the review • Dated Signature of the company representative
Contents page	• A contents page that confirms the full content of the file • If a specific section is not relevant to the review, the contents page will state so • Statements on appendices and supporting documents to each section
Documentation file	• A copy of the technical documentation, including all appendices and supporting documents • Do not submit one document with many pages, each section of the TD file must be it's own file as a minimum. Inadequately presented files will either be rejected or additional time will be charged and invoiced. You will be notified of this, to agree which option will be taken.
Copy of the certification currently held	• A copy of the current certification held by the legal manufacturer • If this is the initial certification then a statement is to be made to this effect • Include a copy of the device list
Copy of the signed agreement	• A copy of the signed agreement to which the review relates • Although IMNB will have the agreement, the copy of the agreement is required • Include a copy of any Agreement with Authorised Representative meeting MDR Article 11, when applicable.
Change notification	• If the review is due to a change notification, include a copy of the change notification. • If the review includes the summation of previous change notifications, please provide copies of the change notifications applicable
Submission Paper files, files on CD / DVD or other electronic media not stated below are not permitted, instead electronic submissions are required as follows:	• Hightail – document transfer system You will be provided the access details once the file is requested. All files must be fully searchable and additionally any hyperlinks must be fully functional and allow unrestricted access. Any files that are not in the required format will be rejected and any time spent will be invoiced.

Main and subsections of the TD submission

The following sections of the MDR annex II is expected to be submitted, with sufficient information in each section to understand the content and how the TD file addresses the particular topic.

Where a section is not applicable, please state this and the rationale. Do not delete any sections.

Section	Associated MDR section
Part A – Device Description and Specifications including Variants and Accessories Include a very clear statement with detailed rationale concerning why the product is a medical device (as per article 2 of the MDR)	Annex II Section 1
Part B – Information to be supplied by the Manufacturer	Annex II Section 2
Part C – Design and Manufacturing Information	Annex II Section 3
Part D – General Safety and Performance Requirements	Annex II Section 4
Part E – Benefit-Risk Analysis and Risk Management	Annex II Section 5
Part F – Pre-clinical Information	Annex II Sections 6.1.a, 6.1.b, 6.2.d, 6.2.f
Part G – Clinical Evaluation, PMS and PMCF	Annex II Section 6.1.c, 6.1.d; Annex III
Part H – Information related to - Medicinal Substances incorporated in the device - Animal/Human tissue derivatives or cells or other non-viable biological substances - Substances absorbed by or locally dispersed in the human body (for Rule 21 devices)	Annex II Section 6.2.a – 6.2.c
Part I - Sterilisation and Information related to re-usable surgical instruments	Annex II Section 6.2.e
Part J – Declaration of Conformity	Annex IV
Part K - Specific information for Class III implantable devices, and Class IIb active devices intended to administer or remove medicinal substances as per Rule 12 to determine the need for CECP process	MDCG 2019-3

Note that all documents that require to be signed, must have dated signatures (except for draft DoCs, which cannot be signed or dated), draft documents are not acceptable.

The following provides further assistance in ensuring a full and complete Technical Documentation submission is provided. Where a section is not applicable, please state this and the rationale. Do not delete any sections.

Section Title / Item	Additional Guidance
Device Description and Specifications Including Variants and Accessories	
General description including product or trade names, principles of operation, mode of action etc	Sufficient information to be provided for a full understanding of the device, it's packaging, sterilization properties and any other characteristic and functions necessary to understand the product. Where there are variants, accessories etc.. then sufficient information must be provided to differentiate between the product and the variants, accessories etc.... Photos, schematics, diagrams etc.... which assist in the understanding of the product and it's intended use should be provided. A definition as a medical device, as per article 2 of the MDR is required to be provided. If the product is used with accessories, then please ensure that the information regarding compatibility of the product with the accessories is provided.
Accessories included	Full details of the accessories (including classification) provided and accessories that are necessary to be used with the product, but is not the product is required to be provided, to such an extent as to allow a full understanding of the product and it's intended use. The information to include a description of how they are packaged and any special characteristics to allow a full understanding of the accessories and their intended use. If the product is an accessory to a medical device, then please ensure that the information regarding compatibility of the product with the accessories is provided. A definition of the accessory as a medical device, as per article 2 of the MDR is required to be provided.
Accessories not included but necessary for use	Please state with sufficient detail to understand if there are any accessories not included but necessary for use.

Intended Purpose and Intended Users	
Intended purpose including any clinical claims	Please provide sufficient information regarding the consistent claims (throughout the file) for the intended purpose and the clinical claims for the product. Any warnings, cautions and contraindications must be clearly stated. Intended use statements must demonstrate that the product is a medical device as per article 2 of the MDR.
Intended user(s)	The intended user is to be clearly stated with sufficient detail to confirm that the intended user has been included in all relevant aspects of the file.

Basic UDI-DI & EMDN code	
Basic UDI-DI and any other relevant UDI related information	The details of the basic UDI-DI and other relevant information is to be provided.
EMDN code	European Medical Device Nomenclature code (EMDN code; previously referred to as CND code) should be stated.

Devices covered by the Technical Documentation file	
List of devices including catalogue numbers covered by the Technical Documentation file	The complete list of product codes is to be provided to ensure that the review covers adequately the products in the file.

Classification	
Classification of the device including all the applicable rules and relevant rationales	The full set of classification rules with rationale for classification is to be provided. Where multiple rules apply, please provide information on each rule.

Materials	
Description and identification of key materials incorporated into the device	Sufficient detailed information is required to be provided to ensure a full understanding of the materials incorporated into the device. This would include raw materials, coatings where they are necessary and / or safety critical and / or performance critical. Within the information, please provide sufficient information as to whether the material are in contact with the patient / user and where they are in contact.

Identification of any tissues or cells of human or animal origin that may have been utilised in the manufacture of the device	A clear statement of whether the product includes this material is required to be provided.
Bill of Materials	A copy of the BOM is required

Market History	
Overview of relevant market history of the device (e.g. Date of first making available, Units sold, Previous models, Current and previous regulatory approvals)	A change history for the product is required, including the list of non significant changes, the list of significant changes with a copy of the NB approval for the changes. An overview of the product market history to include sales numbers, market issues, CAPAs associated with the product, etc.....
Overview of similar devices available in EU or other markets	Where the product is available in non EU countries, please provide a list of the non EU markets.

Information Supplied by the Manufacturer	
Language requirements for each member state must be adhered to	
Device or Product labelling	Provide copies of the device or product labelling, with sufficient information such that the full set of labelling for each market (language) is provided. Drawings, photos, schematics is possible as well.
Sterile packaging labelling	Provide copies of the packaging labelling regarding the sterile barrier system, with sufficient information such that the full set of labelling for each market (language) is provided. Drawings, photos, schematics is possible as well.
Single unit packaging labelling	Provide copies of the device or product labelling, with sufficient information such that the full set of labelling for each market (language) is provided. Drawings, photos, schematics is possible as well.
Sales packaging labelling Transport packaging labelling	Provide copies of the device or product labelling, with sufficient information such that the full set of labelling for each market (language) is provided. Drawings, photos, schematics is possible as well.
Instructions for use / Device Operating Manual(s)	Where IFUs or other such similar information is provided to the user / patient, please provide copies of these in each of the languages.
Patient handbook	Where patient handbooks or other such similar information is provided to the user / patient, please provide copies of these in each of the languages.

Physicians handbook	Where physicians handbooks or other such similar information is provided to the user / patient, please provide copies of these in each of the languages.
Implant card information	Where applicable due to the nature of the product, please provide these.
Electronic IFU (e-IFU) information	Where applicable, then full evidence of compliance to Regulation 207/2012 is required.
Copies of promotional materials	Copies of the marketing material is required to be provided where the (CE marked) product is stated, referred to or implied. Any claims must be substantiated within the Technical Documentation file.
Website address where the IFU	This information is required.

Design and Manufacturing Information	
Design Stages	
Summary of design stages applied to the device and for legacy devices, the design and testing history	Sufficient detailed information to understand the design stages is required. Flow charts, procedures, etc... may be sufficient if suitably described. For legacy devices, the design history (and changes) of these devices is required, as well as previous testing relevant to the current product specification and a detailed rationale of why tests no longer applicable are no longer applicable.

Product and Design specifications	
Key product/design specifications of the device	The key product and / or design specifications of the device is required to be provided with sufficient detail as to allow an understanding of the tests. The information provided is to include specifications for the components, raw materials, packaging etc....
User requirements	Clearly stated user requirements is to be provided.

Manufacturing Information	
Manufacturing processes (including outsourced processes)	A detailed description of the manufacturing processes is required, which in addition would include clear statements of the outsourced processes, and where any of the processes is outsourced (internally or externally) details of the supplier is required.
Critical process verification protocols/plans	Critical processes to be stated. Where the process is verified (not validated), then the verification plans, protocols and reports are required). Where processes are validated, then a copy of the master validation plan is required.

Critical process verification reports	Critical processes to be stated. Where the process is verified (not validated), then the verification plans, protocols and reports are required). Where processes are validated, then a copy of the master validation plan is required.
Critical process validation protocols/plans	Critical processes to be stated. Where the process is validated), then the plans, protocols and reports are required. A copy of the master validation plan is required.
Critical process validation reports	Critical processes to be stated. Where the process is validated), then the plans, protocols and reports are required. A copy of the master validation plan is required.
Incoming inspections	The following are required. • Acceptance criteria & results of incoming inspections • Acceptance criteria & results of final inspections from a sample batch for the finished devices • Statement of the test laboratory used (name and addresses) as well as conformation of any accreditation certificate held for the tests performed.
In-process inspections	The following are required. • Acceptance criteria & results of incoming inspections • Acceptance criteria & results of final inspections from a sample batch for the finished devices • Statement of the test laboratory used (name and addresses) as well as conformation of any accreditation certificate held for the tests performed.
Final inspections	The following are required. • Acceptance criteria & results of incoming inspections • Acceptance criteria & results of final inspections from a sample batch for the finished devices • Statement of the test laboratory used (name and addresses) as well as conformation of any accreditation certificate held for the tests performed.
Installation and Commissioning tests	Where applicable, detailed information on the Installation and Commissioning tests required and performed.

Sites involved in design and manufacturing activities	
Legal Manufacturer	Full details of the legal manufacturer including the SRN is applicable.
European Representatives	If applicable the full details of the EU Representative.
Site with Design responsibility	Full details of where design responsibility rests.
Sterilisation subcontractors	Full details of any sterilization subcontractors. Include copies of any certification held.
Other critical subcontractors and suppliers	Full details of any critical subcontractors and suppliers. Include copies of any certification held.

General Safety and Performance Requirements (GSPRs)	
Demonstration of conformity with GSPRs	
GSPR checklist (or any other format)	Documented evidence of meeting the requirements of the GSPR.
Standards applied	Provide the list of standards applied in full or in part. Where applied in part, then detailed information on which parts have been applied. Include the revision status of the standards applied, not just the number.
Common Specifications	If applicable, details of the CSs applied
Other applicable Regulations & Directives (PPE, Machinery, e-IFU regulation etc)	Provide details of any other regulations / directives that are applicable.

Benefit-Risk Analysis and Risk Management	
Benefit-risk analysis	
Benefit-risk analysis	The detailed discussion and rationale for the clinical benefit outweighing the risk of the product is required.

Risk Management	
Risk management procedure	Provide copies of the relevant risk management documentation to confirm that the risk management procedure is followed. This would include a copy of the procedure.
Risk management plan	A copy of the risk management plan is required.

Risk scoring system	A copy of the risk scoring system is required. This may be the procedure, the plan or elsewhere where the risk scoring system used is described.
Design risk assessment	A copy of the design risk assessment is required.
Production/process risk assessment	A copy of the production process risk assessment is required.
Clinical/Application/Product risk assessment	A copy of the clinical application / product risk assessment is required.
Risk management report	A copy of the risk management report is required.
Risk management personnel competency	Please provide evidence of the competency ie CV's / Training records, etc...

Product Verification and Validation	
Biocompatibility	
Biological evaluation report	A copy of the protocol / plan and report is required.
Biological safety risk assessment	A copy of the biological safety risk assessment for the device is required.
Material characterisation test protocols and reports	Material characterisation test protocols and reports are required, special attention to GSPR 10.4.1 for carcinogenic, mutagenic or toxic materials (CMR) is required.
Biocompatibility test protocols and reports	The report including the rationale for classification, test reports etc.. is required. Importantly where any tests were not conducted, the rationale for not conducting the tests is required.
Overall biological safety assessment	Evidence of the finished, packaged (sterilized if device is sterile or to be sterile) to be biologically safe is required. Material / component only testing is not sufficient, the finished device is required.
CVs of the expert assessors involved in the biological safety assessment to establish competence	Evidence of the competency of the test facility / assessors involved in the biological safety assessment is required.

Electrical safety and electromagnetic compatibility (EMC)	
Electrical safety test protocols	Copies of the test protocols and the name and address of the test laboratory conducting the test is required. Evidence of their accreditation is required. For inhouse testing, evidence of the competency of the personnel involved is required.
Electrical safety test reports	Copies of the test reports and the name and address of the test laboratory conducting the test is required. Evidence of their accreditation is required. For inhouse testing, evidence of the competency of the personnel involved is required.
EMC test protocols	Copies of the test protocols and the name and address of the test laboratory conducting the test is required. Evidence of their accreditation is required. For inhouse testing, evidence of the competency of the personnel involved is required.
EMC test reports	Copies of the test reports and the name and address of the test laboratory conducting the test is required. Evidence of their accreditation is required. For inhouse testing, evidence of the competency of the personnel involved is required.

Software Verification and Validation	
Test protocol	Copies of the test protocols and the name and address of the test laboratory conducting the test is required. Evidence of their accreditation is required. For inhouse testing, evidence of the competency of the personnel involved is required. A clear statement and documented rationale as to why the product is a Software as a Medical Device (SaMD) is required.
IEC 62304 checklist	If compliance with IEC 62304 is claimed, then a checklist should be provided to demonstrate which document should be considered to demonstrate compliance with each clause. If a different standard has been used, then a rationale should be provided to explain how the requirements of IEC 62304 have been met or exceeded. If the software is for use with mobile platforms, information demonstrating compliance with GSPR 17.3. should be provided.
Software development plan	Copies of the development plan is required.
Software requirements analysis	Copies of the requirements analysis is required.
Software architectural design	Details of the architectural design is required.

Software detailed design	Copies of the detailed design is required including classification with rationale for the software is required.
Software unit implementation and verification	Evidence of the implementation and verification is required.
Software integration and integration testing	Evidence of the integration and testing is required.
Software systems testing	Evidence of the system testing is required, with details of any amendments made.
Software release	Details on the software release is required, which would include build status, errors etc....
Software risk assessment	Evidence of the risk assessment is required.
Cybersecurity documentation	Details on the cybersecurity is required, including threats, confidentiality, integrity, availability, risk plan, risk assessment, verification / validation for the risk controls.

Stability, including shelf life	
Stability/shelf-life validation protocols (to include both device and packaging performance)	Evidence that product characteristics are maintained for the whole of the shelf life (including shipping / distribution) is required. Protocol, reports, material specifications are required.
Stability/shelf-life validation results and reports	Evidence that product characteristics are maintained for the whole of the shelf life (including shipping / distribution) is required. Protocol, reports, material specifications are required.

Performance and Safety - Design Verification and Validations	
Design control matrix	The design verification, validation, summary of results is required for each design criteria, whether by testing or otherwise. If otherwise, the detailed rationale for no testing is required. Legacy devices require detailed rationale why previous testing is currently applicable.
Design requirements	Documented design requirements for the device is required.
Verification and validation plan	The V&V plan is required.

Verification protocols and results	Protocols and reports are required. Where previous results are used for new / different products, the documented rationale is required.
Validation protocols and results	Protocols and their results are required.
Usability study protocols and results	Protocols and their results are required.
Evidence to support the device lifetime in use	Protocols and their results are required.
Sample Size Procedures	Documented rationale for the sample size used is required.

Clinical Evaluation	
Clinical development strategy	Please provide the clinical development strategy for the device. Include copies of the pre clinical and the clinical evaluation procedures.
Clinical development plan	Please provide the clinical development plan for the device.
Clinical evaluation plan	Please provide the clinical evaluation for the device.
Clinical evaluation report (CER)	Please provide the CER with all supporting documentation.
CVs and Declaration of Interests (DoI) of the relevant personnel associated with the Clinical evaluation report	Copies of the CVs and DoIs required.
Clinical investigation protocols	Where Clinical Investigation is conducted, copies of the protocols, ethics committee approvals, Investigator's brochure etc... are required.
Clinical investigation results	Where Clinical Investigation is conducted, copies of the reports, ethics committee approvals etc... are required.
Statistical analysis plans	Where Clinical Investigation is conducted, copies of the statistical analysis plans is required.
Copies of literature articles	Copies of the literature articles used is required.
Summary of Safety and Clinical Performance	Summary of Safety & Clinical Performance (SSCP) must be provided where required by the MDR.

Post Market Surveillance & Post Market Clinical Follow-up	
Post Market Surveillance data (Market History, worldwide and EU sales volumes, Complaints data and trend analyses; Vigilance data and trend analyses; data from other PMS sources)	Post market Surveillance data is required going as far back as the certificate issue / renewal which may be 5 years.
Post market surveillance plan	A Post-Market Surveillance Plan (PMS Plan) for the product is required.
Periodic Safety Update Reports (if available)	Where required by the MDR, a copy of the PSURs is required.
Post market clinical follow-up (PMCFU) plan & protocols	Where PMCFU is applicable, a copy of the plan and protocol is required.
Post market clinical follow-up reports	Where PMCFU is applicable, a copy of the plan and protocol is required.

Devices incorporating medicinal substances	
Overview	Where applicable to the device then: Module 1 of MEDDEV 2.1/3 and CTD headings is required.
Medicinal substance	Where applicable to the device then: Statement on the medicinal substance with copy of the CEP / ASMF/ PMF and letter of access is required.
Device: 3.2.P Module 3 including development, manufacture, intermediate and end product specifications and tests, and stability.	Where applicable to the device then: Module 3: 3.2.P is required.
Module 4: Non-clinical data relating to the medicinal substance and device	Where applicable to the device then: Module 4 is required.
Module 5: Clinical data relating to the safety and efficacy of the medicinal substance	Where applicable to the device then: Module 5 is required.
Device IFU and labelling	Where applicable to the device then: Copies of the IFU and labelling.

Devices utilising tissue and cells of human or animal origin or their derivatives or other non-viable biological substances (as per GSPR 13.3)	
Information on the nature of the animal starting tissue, animal species and geographical nature	Where applicable to the device then: Details about the animal / human tissue material.
Animal/Human tissue (or their derivatives) related risk assessment	Where applicable to the device then: Details about the risks associated animal / human tissue material.
Justification for the use of animal/human tissues or their derivatives	Where applicable to the device then: Justification for the use animal / human tissue material.

Devices composed of substances that are absorbed by or locally dispersed in the human body	
Test protocols for determining the absorption, distribution, metabolism, excretion of those substances	Copies of the test protocols are required.
Test reports and data for determining the absorption, distribution, metabolism, excretion of those substances	Copies of the test reports and test data are required.
Test protocols for determining the local tolerance	Copies of the test protocols are required.
Test reports determining the local tolerance	Copies of the test reports are required.
Test protocols for determining the possible interactions of those substances, products of metabolism in the human body, with other devices, medicinal products or other substances	Copies of the test protocols are required.
Test reports for determining the possible interactions of those substances, products of metabolism in the human body, with other devices, medicinal products or other substances	Copies of the test reports are required.
Test protocols for determining the toxicity of those substances	Copies of the test protocols are required.
Test reports for determining the toxicity of those substances	Copies of the test reports are required.

Devices containing CMR or endocrine-disrupting substances referred to in GSPR 10.4.1 of Annex I of MDR	
Data related to the estimation of potential patient or user exposure to the substances	Documented rationale for this item is required.
Information/data on analysis of possible alternative substances, materials or designs	Information on the alternative substances to CMRs / endocrine disrupting substances.
Rationale for the presence of CMR and/or endocrine-disrupting substances	Documented rationale for the presence of CMRs.
Labelling	Copies of the labelling required.

Packaging and Transit (Transport) testing	
Packaging drawings and/or configurations	Detailed description of the packaging and configuration is required.
Packaging validation protocols	Copies of the test protocols required.
Packaging validation reports	Copies of the test reports required.
Transit/transport testing protocols	Copies of the test protocols required.
Transit/transport testing reports	Copies of the test reports required.

Sterilisation	
Sterilisation Validation protocol	Copies of the protocol required.
Sterilisation Validation results and reports	Copies of the test results and reports required.

Reusable surgical instruments	
Cleaning, Disinfectant, Sterilisation Validation Protocols and IFU	Copies of the test protocols and IFU is required.
Cleaning, Disinfectant, Sterilisation Validation reports and IFU	Copies of the test results and IFU required.

Devices with a measuring or diagnostic function	
Protocols	Copies of the protocols required.
Reports	Copies of the report required.

Devices intended to be connected to other devices to operate as intended	
Protocols	Copies of the test protocols required.
Reports	Copies of the test results required.

Magnetic resonance imaging safety of implants	
MRI safety test protocol	Copies of the test protocols required.
MRI safety test results	Copies of the test results required.
MRI safety labelling	Copies of the safety labelling required.

Declaration of Conformity	
Draft Declaration of conformity – initial certification	Draft unsigned DoC required.
Signed Declaration of conformity – surveillance reviews	Signed DoC required.

Review process

- On receipt of the Technical Documentation file, the file will be allocated for review, the file will undergo a content validation stage, where a check of the stated contents have been received (no technical review will take place at this stage).
- After successful completion of the content validation, a pre-assessment of the technical documentation will be undertaken to confirm if there are any specific issues or focus for the review. It is at this stage that the extent of the review will be confirmed (resource needs, In House Clinician oversight etc....).
- On successful completion of both the content validation and pre-assessment the file will be subject to the Technical review.

- If at any stage the file is not in a reviewable format, inadequately presented files will either be rejected or additional time will be charged and invoiced. You will be notified of this, to agree which option will be taken. .

Note that the date of requesting the receipt of the Technical Documentation file does not imply in any way that the file will be subject to an immediate review, there may be some time between requesting the receipt by a certain date and the commencement of the review. Our Operations team will advise when the file is scheduled to commence.

During the review stages, it may be necessary to request additional documentation, information, seek clarification, which may take place outside of any specific defined review stages. Therefore it is in the best interest of the project that you respond adequately and with urgency to these requests, and any due dates requested must be adhered to, so as to ensure that the validity of the certificate is not at risk.

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 44,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

FOR MORE INFORMATION

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For over 130 years, businesses around the world have trusted us to ensure the quality and safety of their products and processes.

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