# Reference No. JN 2020-221

# TECHNICAL SPECIFICATIONS

1. **The subject matter of the tender/the description of the subject matter of the tender:**

The subject matter of the public tender is the procurement of personal protective equipment for the stocks to be established in accordance with the Decision adopted by the Government of the Republic of Slovenia No. 01201-7/2020/5 as of 8 July 2020. The tender is divided in 6 lots.

Quality requirements:

**LOT 1: Medical face masks – class FFP3 particulate respirators: 108,900 pieces**

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| Product description |
| **General description:** A non-sterile disposable product for single use**,** it shall protect the wearer from exposure to aerosols, dust particles and microorganisms**,** it has to be shaped to adapt to many face shapes for a snug fit and it shall cover the nose, mouth and chin; it shall feature two fixing elastic headbands**,** the nose clip has to be efficient, adequately large and pliable for adjustment**,** the length of thenose clip shall be no less than 9 cm**,** the internal layer of the medical face mask has to be comfortable to wear and it shall not cause any irritation or allergic reactions; the medical face mask shall prevent free circulation of air on the sides, it shall not make breathing difficult, i.e. it shall not obstruct breathing (good breathability), the level of protection shall be FFP3.  **Material:** A FFP3 face mask shall be made of a non-woven material/fabric**,** the material/fabric shall be spunbonded, the core of the medical face mask shall preserve its shape when the wearer inhales and exhales, it shall be odourless and latex-free, not easily flammable.  **Packaging:** Each item shall be individually wrapped up and up to 20 pieces shall be placed in cardboard packaging that enables easy opening and straightforward taking out a single item; the information shown on the internal and on the external side of the packaging shall include: the name of the manufacturer, the name of the product, the item catalogue number, lot number, number of pieces in the base packaging, shelf-life/expiry date, CE marking, EN standard, protection class, face mask type;several layers of inner packaging shall be placed in a robust outer packaging for transportation.  **EU norms and standards, i.e. requirements:** In conformitywith the Council Directive 93/42/EEC**,** European StandardEN 14683**,** European Standard EN 149:2001+A1:2009 **HARMONISED STANDARDS under Directive 89/686/EEC;** there shall be the CE marking. |

**LOT 2: FACE SHIELD/VISOR USED BY HEALTH WORKERS: 34,083 pieces**

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| Product description |
| A single use/disposable product intended for use in the course of the procedures associated with a risk of the health workers being exposed to splashes of blood/bodily fluids, i.e. droplet/aerosol transmission to the eyes.  The face shield/visor shall be manufactured from clear/transparent polyester film, without any glare/reflection and clouding on both sides. The headband shall feature a silicone strap, the face shield/visor shall be latex-free and without DEHP.  In accordance with the Council Directive 93/42 EEC, ISO 13485, it is classified as a Class I device. |

**LOT 3: MEDICAL GOWN USED BY HEALTH WORKERS: 263,265 pieces**

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| Product description |
| **General description:** A non-sterile disposable product for single use**,** without DEHP**,** latex-free,the isolation gown shall provide equivalent protection of the body front, of the back and on the seams; the seams shall be welded/sealed and not sown; the protection grade according to the relevant standard shall be displayed on the gown; it shall be impermeable to fluids, it shall have with long sleeves tightened around wrists, without cuffs;simple, efficient and trouble-free closure on the back with a neck tie and waist tie/belt, colour: blue.  **Material:** These gowns shall be made of a non-woven barrier fabric**,** impermeable to fluids**,** impermeable tomicroorganisms and dust particles**,** it shall preserveits characteristics when both wet and dry, grammage: minimum 30 g/ m2**,** the spunbonded fabric that does not fray and does not shed filaments**,** does not irritate the skin**,** has no odour**,** contains no latex**,** doesnot give rise to sustained burning.  **Size:** European L, XL sizes.  **Packaging:** Each item shall be individually wrapped up, i.e. up to 10 pieces can be packed together; the information shown on the internal and on the external side of the packaging shall include: the name of the manufacturer, the name of the product, the item catalogue number, lot number, number of pieces in the base packaging, shelf-life/expiry date, CE marking; several layers of inner packaging placed shall be placed in a robust outer packaging for transportation.  **EU norms and standards, i.e. requirements:** In conformitywith the Council Directive 93/42/EEC**,** Directive 89/686/EEC**,** EN ISO 13485;there shall be the CE marking. |

**LOT 4: APRON / WITH SLEEVES: 950,000 pieces**

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| Product description |
| **General description:** A disposable product for single use,non-sterile, latex-free**,** blue colour, withoutDEHP**,** completely madeof the material/fabric impermeable to fluids of 100% polyethylene complete with a neck tie, the sleeves with thumb openings, the waist ties, full protection of the shoulder area and open back.  **Size:** Thickness > 40 cm**,** length (from the collar down) >120 cm**,** sleeve length (from the armpit to the bottom hem) >60 cm.  **Packaging:** 1 piece in individual wrapping and up to 200 pieces in the cardboard packaging**,** the information shown on the internal and on the external side of the packaging shall include: the name of the manufacturer, the name of the product, the item catalogue number, lot number, number of pieces in the base packaging, CE marking; several layers of inner packaging placed shall be placed in a robust outer packaging for transportation, shelf-life/expiry date, ‘open here’ marking, CE marking, EN standard.  **EU norms and standards, i.e. requirements:** In conformitywith the Council Directive 93/42/EEC**,** Directive 89/686/EEC;there shall be the CE marking. |

**LOT 5: PROTECTIVE HEAD COVER: 312,000 pieces**

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| Product description: BONNET |
| **General description:** A disposable product for single use**,** cut out in one piece**,** complete withsoft elastic latex-free, braided with polyester thread that after being worn for prolonged periods of time does not cause pressure, fits the head nicely, colour light green or light blue.  **Material:** Non-woven material/fabric made of 100% polypropylene filaments**,** minimumgrammage 14 g/m2; the spunbonded fabric that does not fray and does not shed filaments**,** it shall be airy**,** it shall not irritate the skin**,** it is odourless**,** it is latex-free**,** doesnot give rise to sustained burning.  **Size:** Thediameter of the stretched non-woven fabric for the bonnet shall be approximately 55-60 cm.  **Packaging:** Up to 100 pieces placed in the cardboard internal packaging that enables an individual item to be easily pulled out; the information shown on the internal and on the external side of the packaging shall include: the name of the manufacturer, the name of the product, the item catalogue number, lot number, number of pieces in the base packaging, shelf-life/expiry date, ‘open here’ marking, CE marking; several layers of inner packaging placed shall be placed in a robust outer packaging for transportation.  **EU norms and standards, i.e. requirements:** In conformitywith the Council Directive 93/42/EEC**,** in conformity with theDirective 89/686/EEC;there shall be the CE marking. |

**LOT 6: PROTECTIVE SHOE COVER: 250,000 pieces**

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| Product description: PROTECTION FOR SHOES ONLY |
| **General description:** A disposable product for single use**,** the opening braided with elastic thread**,** tightly fits a shoe and covers it completely.  **Material:** Non-woven material/fabric made of 100% propylene filaments**,** it shall not frey, it shall be water repellent**,** non-slippery material**,** does not give rise to sustained burning**.**  **Size:** Adjustedto fit footwearsize 35 to 50.  **Packaging:** Up to 100 pieces placed in internal packaging that enables an individual item to be easily pulled out; the information shown on the internal and on the external side of the packaging shall include: the name of the manufacturer, the name of the product, the item catalogue number, number of pieces in the base packaging, shelf-life/expiry date, wording: sterile product, CE marking; several layers of inner packaging placed shall be placed in a robust outer packaging for transportation.  **EU norms and standards, i.e. requirements:** In conformity with the Council Directive 93/42 EEC, European Standard EN 1149-1:2006, **HARMONISED STANDARDS under Directive 89/686/EEC;** there shall be theCE marking. |

The personal protective equipment (PPE) shall comply with all relevant regulations and standards in force and have all approvals mandatory in the Republic of Slovenia for such a product, which the tenderer **shall demonstrate by submitting certificates, EU declarations of conformity, technical lists/files and other documents** at the time of the tender submission and the delivery.

Furthermore, the tenderer hereby undertakes when called upon by the contracting authority/procuring entity:

* To submit a representative sample of the products offered;
* To provide additional clarifications concerning technical and other characteristics of the products offered;
* To make the arrangement for his representative to participate in person in the comparison of the sample against the requirements set out in the procuring entity’s description of the product offered.

***Personal protective equipment (PPE)*** *is the subject matter of the Regulation (EU) 2016/425 and of the Decree on the implementation of the Regulation (EU) on personal protective equipment [Uredba o izvajanju Uredbe (EU) o osebni varovalni opremi] (Official Gazette of the Republic of Slovenia, No. 33/18). The body competent for the supervision of the market in Slovenia is the Market Inspectorate.*

*PPE must fulfil the essential health and safety requirements. The manufacturers of PPE may adopt specific technical solutions for their production, which are specified in detail in the relevant harmonised standards.*

***Medical devices*** *are regulated in the Republic of Slovenia by the Medical Devices Act [Zakon o medicinskih pripomočkih] (Official Gazette of the Republic of Slovenia, No. 98/09; ZMedPri) and its acts of secondary legislation, by virtue of which the provisions set out in the Directive 93/42/EEC concerning medical devices have been transposed into the legal order of the Republic of Slovenia. They are intended to be used by healthcare workers in health institutions or by other persons for medical purposes. The jurisdiction over medical devices is exercised by the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP). Conformity with legislation regulating medical devices and conformity with the essential requirements concerning safety and efficiency shall be established by the manufacturer that on the basis of the established conformity shall draw up the EU declaration of conformity and on the products, that is, on the packaging shall affix the CE marking (the CE marking of conformity is specified and shown in Annex XII to the Council Directive 93/42/EEC concerning medical devices and stands for Conformité Européenne – European Conformity). The manufacturers of PPE may adopt specific technical solutions for their production, which are specified in detail in the relevant harmonised standards.*

*The manufacturer from a third country must appoint an authorised representative before making personal protective equipment available on the Union market (including the market of the Republic of Slovenia). The authorised representative is an economic operator with the mandate to act on behalf of the manufacturer, keep the technical documentation and the declarations of conformity at the disposal of the competent authorities and communicate, that is, cooperate with the competent authorities. The manufacturer from a third country may have only one authorised representative in the EU. An economic operator who primarily procures/sells/places a certain medical device from a third country on the Union market is the importer (providing that he arranges logistics for the supply of medical devices from a third country), that is, a distributor, provided that he makes a medical device from any other EU Member State available on the market of the Republic of Slovenia.*

*As an authorised representative, importer, distributor, the economic operator must notify his activity to the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP). The authorised representative with the registered office in the Republic of Slovenia must register the medical devices in the register of medical devices in addition to the registration of the activity with the JAZMP.*

*An importer must fulfil the obligations laid down in Article 54 of the Medical Devices Act [Zakon o medicinskih pripomočkih] (ZMedPri) and in the second chapter of the Rules on the manufacturing and trade in medical devices [Pravilnik o proizvodnji in prometu z medicinskimi pripomočki] (Official Gazette of the Republic of Slovenia, No. 37/10).*