Ministry of Healthcare

DIRECTORATE GENERAL OF PREVENTION

TO
Cabinet Office
Headquarters

Civil Protection
Coordinamento.emergenza@protezionecivile.it
protezionecivile@pec.governo.it

Ministry of Economy and Finance
mef@pec.mef.gov.it

Ministry of Economic Development
gabinetto@pec.mise.gov.it

Ministry of Infrastructure and Transport
ufficio.gabinetto@pec.mit.gov.it

Ministry of Work and Social Policies
segreteriaministro@pec.lavoro.gov.it

Ministry of Culture
mbac-udcm@mailcert.beniculturali.it

Ministry of Tourism
ufficiodigabinetto.turismo@pec.it

Ministry of Foreign Affairs and International Cooperation
gabinetto.ministro@cert.esteri.it

Ministry of Defence General Inspectorate of Military Health
stamadifesa@postacert.difesa.it

Ministry of Education
uffgabinetto@postacert.istruzione.it

Ministry of University and Research
uffgabinetto@postacert.istruzione.it

Ministry of the Interior
gabinetto.ministro@pec.interno.it

Ministry of Justice
capo.gabinetto@giustiziacert.it

Prison Administration Department

Directorate General for Prisoners and Treatment
Ministry of Justice
prot.dgdt.dap@giustiziacert.it
gabinetto.ministro@giustiziacert.it

Ministry of Economic Development
gabinetto@pec.mise.gov.it

Ministry of Agriculture, Food and Forestry
ministro@pec.politicheagricole.gov.it

Ministry of the Environment and Protection of the Territory and the Sea
segreteria.ministro@pec.minambiente.it

Presidency of the Council of Ministers - Department of Regional Affairs and Autonomies
affariregionali@pec.governo.it

Departments of Health of Ordinary and Special Statute Regions
TO THEIR HEADQUARTERS

Departments of Health of Autonomous Provinces of Trento and Bolzano
TO THEIR HEADQUARTERS

National Association of Italian Municipalities (ANCI)
anci@pec.anci.it

U.S.M.A.F. – S.A.S.N. Maritime, Air and Border Health Offices
TO THEIR HEADQUARTERS

National Office for the Pastoral Care of Health Italian Episcopal Conference
salute@chiesacattolica.it

Rev. Massimo Angelelli
Director of National Office for Pastoral Care
m.angelelli@chiesacattolica.it

National Federation of the Order of Surgeons and Dentists Modena
segreteria@pec.fnomceo.it

FNOPI National Federation of the Orders of Nursing Professions
federazione@cert.fnopi.it

FNOPO National Federation of the Orders of Midwives
presidenza@pec.fnopo.it

FOFI Federation of the Orders of Italian Chemists
posta@pec.fofi.it

Directorate General for Medical Devices and Pharmaceutical Service DGDMF
HEADQUARTERS

National Federation of Orders of Medical Radiology Health Technicians and Technical Health Professions, Rehabilitation and Prevention
federazione@pec.tsrm.org

Hospital and University Hospital Centre Luigi Sacco
protocollo.generale@pec.asst-fbf-sacco.it

Carabineer Unit for the Protection of Health – NAS

srm20400@pec.carabinieri.it

National Institute of Health (ISS)
protocollo.centrale@pec.iss.it

National Institute for Infectious Diseases – IRCCS "Lazzaro Spallanzani"
direzionegenerale@pec.inmi.it

Medical Radio International Centre (CIRM)
fondazionecirm@pec.it

National Institute for the promotion of health of migrating populations and to fight poverty diseases (INMP)
inmp@pec.inmp.it

Federation of Italian Medical and Scientific Societies (FISM)
fism.pec@legalmail.it

Confartigianato
presidenza@confartigianato.it

National Blood Centre
cns@pec.iss.it

National Transplantation Centre

cnt@pec.iss.it

CONFCOMMERCIO
confcommercio@confcommercio.it

ITALO - Nuovo Trasporto Viaggiatori SpA
italo@pec.ntvspa.it

Directorate General Health Planning
DGPROGS
HEADQUARTERS

SIMIT – Italian Society of Infectious and Tropical Diseases
segreteria@simit.org

Italian Society of Hygiene, Preventive Medicine and Public Health (SItI)
siti@pec-legal.it

Italian Society of Medicine and Prison Health (Simspe-onlus)
Via Santa Maria della Grotticella 65/B
01100 Viterbo

National Order of Biologists
protocollo@peconb.it

ANTEV National Association of Verification Technicians - PRESIDENT

presidente@antev.net

Italian Society of Anaesthesia Analgesia Resuscitation and Intensive Care

siaarti@pec.it

National agency for regional health services
AGENAS
agenas@pec.agenas.it

National Federation of Orders of CHEMISTS and PHISICS
segreteria@pec.chimici.it

Department of Family Policy ROME
segredipfamiglia@pec.governo.it

Veneto Region – Department of Regional Health Prevention Interregional Coordination of Prevention
francesca.russo@regione.veneto.it
coordinamentointerregionaleprevenzione@regione.veneto.it

SUBJECT: Certificates of exemption from COVID-19 vaccination

The provisions of this circular apply exclusively in order to allow access to the services and activities referred to in Art. 3, paragraph 1 of Decree Law no. 105 of 23 July 2021 to subjects who for medical condition cannot receive or complete the vaccination to obtain a COVID-19 pass (green pass).

Pending the adoption of the provisions referred to in the aforementioned decree, the certificates of exemption from Sars-Cov-2 vaccination may be issued in paper form and may be valid until 30 September 2021, unless further provisions; based on the basis of the relevant clinical assessments, the period of validity will be updated when the national digital emission system is launched in order to allow its digital verification.

Temporarily and until 30 September 2021, unless further provisions, the certificates of vaccination exclusion already issued by the Regional Health Services are valid on the national territory. In the meantime, the regions will re-evaluate these certifications in the light of the criteria and content of this circular.

Certificates of exemption from SARS-COV-2 vaccination

SARS-COV-2 vaccination exemption certification (hereinafter referred to as “certificate") shall be issued in the event that vaccination is omitted or deferred due to the presence of specific documented clinical conditions, for which it is permanently or temporarily contraindicated.

Persons who are exempted from Sars-Cov-2 vaccination should be adequately informed about the need to continue to maintain preventive measures such as: using masks, distancing themselves from non-cohabiting persons, wash hands, avoid gatherings in particular in enclosed spaces, comply with the conditions laid down for workplaces and means of transport.

Issuing procedures of certificates of exemption from SARS-CoV-2 vaccination

Until 30 September 2021 and unless otherwise specified, the certificates may be issued directly by the vaccinating doctors of the Vaccine Services of the Companies and Regional Health Services Bodies or by the General Practitioners or Paediatricians of the patient, who operate as part of the SARS-Cov-2 national vaccination campaign. The certification must be issued free of charge, taking care to file the relevant clinical documentation, even digitally, through the regional vaccine information services in ways defined by the individual Regions/ Public Administrations, also for their monitoring.

Certificates shall include:

- identification data of the subject involved (name, last name, date of birth);

- the Italian wording: “soggetto esente alla vaccinazione anti SARS-CoV-2. Certificazione valida per consentire l’accesso ai servizi e attività di cui al comma 1, art. 3 del DECRETO-LEGGE 23 luglio 2021, n 105” (subject exempt from SARS-COV-2 vaccination. This certificate allows access to the services and activities referred to in Art. 3, paragraph 1 of Decree Law no. 105 of 23 July 2021);
- the end-of-validity date of the certificate, using the following Italian wording “certificazione valida fino al_ ” (certificate valid until_) (state the date, maximum up to 30 September 2021);
- Data relating to the Vaccination Service of the Companies and Bodies of the Regional Health Service in which it operates as COVID-19 vaccinator (Service name - Region);
- Stamp and signature of the certifying doctor (even digital);
- Number of enrolment in the order or tax code of the certifying doctor.

Certificates shall not include any other sensitive data of the subject involved (e.g. clinical reason for the exemption).

These certificates may also be used through regional platforms already in charge for issuing vaccination certificates and certificates stating any vaccination unsuitability.

Monitoring the issuing of SARS-CoV-2 vaccination exemption certificates

Pending the adoption of the decree referred to in Art. 3, paragraph 1 of the Decree-Law of 23 July 2021, the Regions and the Public Administrations activate a monitoring system of exemptions issued by communicating, on request, the data in aggregate format to the Ministry of Health.

SARS-CoV-2 vaccination: main contraindications and precautions

A **contraindication** is a condition in the recipient that increases the risk of serious adverse reactions. In general, vaccination should not be administered when there is a contraindication because the risk of adverse reactions is greater than the benefits of vaccination. This assessment shall relate to the specific type of vaccine to be administered. The presence of a contraindication to a specific vaccine does not exclude the possibility that other available vaccines may be administered.

A **precaution** is a condition in the recipient that can increase the risk of serious adverse reactions or compromise the ability of the vaccine to induce an adequate immune response. In general, when a precaution is present, it may be necessary to further explore the individual case by assessing the benefit/risk ratio. This assessment shall relate to the specific type of vaccine to be administered. The presence of a precaution referred to a specific vaccine does not exclude the possibility that other available vaccines may be administered. Most people who at the time of the vaccination

session have a precaution to COVID-19 vaccination may be vaccinated, but in some cases consultation with the attending doctor or specialist should be considered to determine whether the person can receive the vaccination safely.

The accurate collection of the history and assessment of the presence of a contraindication or precaution should be carried out whenever a vaccine is to be administered, even if the same vaccine has already been administered to that person.

In relation to medical conditions that may more frequently result in a postponement or non-vaccination, the main conditions or situations that may or may not represent a contraindication and precaution against Sars-Cov-2 vaccination shall be reported;

Given the complexity of the subject matter, the conditions are not exhaustive; in order to support vaccinating doctors in the assessment of vaccination suitability, Regions and PAs promote the identification at the Vaccination Centres or other ad hoc centres of technical references for how cases of doubt should be taken charge of, and a regional technical group of vaccination experts. The Directorate-General for Prevention will set up a national table to compare the contacts of these technical groups, in order to collectively assess any particular cases.

The following table shows the contraindications reported in the Summary of Product Characteristics (RCP - Riepilogo Caratteristiche di Prodotto) of the vaccines currently used in Italy:

Vaccine	Contraindications
Comirnaty (Pfizer-Biontech)	- Hypersensitivity to the active substance or to any of the excipients (section 6.1 of RCP)
Spikevax (Moderna)	- Hypersensitivity to the active substance or to any of the excipients (section 6.1 of RCP)
Vaxzevria (Astrazeneca)	- Hypersensitivity to the active substance or to any of the excipients (section 6.1 of RCP) - Subjects with thrombotic syndrome associated with thrombocytopenia following vaccination with Vaxzevria; - Subjects who previously had episodes of capillary loss syndrome.
Janssen (J&J)	- Hypersensitivity to the active substance or to any of the excipients (section 6.1 of RCP) - Subjects who previously had episodes of capillary loss syndrome.

Sever allergic reaction following a dose of vaccine or any vaccine ingredient.

A sever allergic reaction following a dose of vaccine or any vaccine ingredient constitutes a contraindication to the administration of further doses of the same vaccine or of products containing the same ingredients. This type of allergic reaction occurs almost always within 30 minutes of vaccination, although cases of anaphylaxis occurring within 24 hours are also attributable to vaccine. In the event of a severe allergic reaction to the first dose of a COVID-19 vaccine, the possibility of using a different vaccine to complete immunisation may be considered; however, given the possibility of cross-reactions between different vaccine components, allergy advice and

individual risk/benefit assessment should be carried out.

Pregnancy

Vaccination against SARS-CoV-2 is not contraindicated during pregnancy. If, after medical evaluation, the decision is to postpone the vaccination, a certificate of temporary exemption to vaccination may be issued to the pregnant woman.

Breastfeeding

Breastfeeding is not a contraindication to SARS-CoV-2 vaccination.

Guillain-Barré syndrome.

Guillain-Barré syndrome has rarely been reported following vaccination with Vaxzevria. In the case of Guillain-Barré syndrome which has arisen within 6 weeks of the administration of the COVID-19 vaccine, without any other traceable cause, it is prudent not to perform further administration of the same vaccine. In such situations, the use of a different vaccine to complete immunisation should be considered.

Myocarditis/pericarditis.

After vaccination with COVID-19 mRNA vaccines (Pfizer and Moderna) very rare cases of myocarditis and pericarditis were observed.

The decision to administer the second dose of Pfizer or Moderna vaccine in persons who have developed a myocarditis/pericarditis after the first dose should take into account the clinical conditions of the individual and should be made after cardiological advice and careful risk/benefit evaluation.

In this situation, where it has been assessed not to proceed with the second dose of COVID-19 mRNA vaccine, the use of a different vaccine to complete immunisation should be considered.

Serological tests.

It is reiterated that serological tests to detect the antibody response to the virus are not recommended for the vaccination decision-making process; for this reason the presence of an antibody titre cannot be considered, at the moment, alternative to the completion of the vaccination cycle.

THE DIRECTOR GENERAL
*signed Dr Giovanni Rezza

The Office Director 05
Dr Francesco Maraglino

Person in charge of the procedure:
Dr Andrea Siddu
a.siddu@sanita.it

***handwritten signature replaced by printing, under Art. 3, paragraph 2 of Leg. Decree. No. 39/1993"*