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, interchangeable) and pdf “ non- type a” for needles and container closure systems. additional guidance for niss equipped with electronic or electromechanical components and niss equipped with automated functions is given in isoand isorespectively. iso:, introduced the concept of interchangeability and the labelling designations “ type a” (i. in order to support device innovation and design, this document has been written in a format that describes the output of the design effort.
it applies iso 11608 pdf to devices intended for patient or caregiver administration of medicinal products to humans. 3 life- cycle testing. this document specifies requirements and test methods for needle-based injection systems (niss) for single- patient use intended to deliver discrete volumes (bolus) of medicinal product, which pdf can be delivered through needles or soft cannulas for intradermal, subcutaneous and/ or intramuscular delivery, incorporating pre- filled or user- filled, replaceable or non-replaceable containers. covered in this part of iso 11608 include single- and multi- dose syringe- based and cartridge- based systems, filled either by the manufacturer or by the end- user. iso– needle- based injection systems. 8 functional stability.
this third edition cancels and replaces the second edition (iso:), which has been technically revised. — part 4: requirements and test methods for electronic and electromechanical pen- injectors. iso:, introduced the concept of interchangeability. the main changes are as follows: — relocation of content to the other parts of the iso 11608 series, as appropriate (see figure 1) ; — added language to address the case when a platform nis is applied for different therapeutics or. these injections are performed manually, through exertion of force by the user, or. iso: specifies particular requirements to make needle- based drug delivery systems or nis (needle- based injection system) accessible for persons with visual impairments. needle- free injectors, and requirements relating to methods or equipment associated with end- user filling of containers, are outside the scope of this part of iso. iso: specifies requirements and test methods for needle- based injection systems (niss) intended to be used with needles and with replaceable or non- replaceable containers.
— part 3: finished containers. this part of iso 11608 include single- and multi- dose syringe- based and cartridge- based systems, filled either by the manufacturer or by the end- user. every interested party, which is member of an organization based in luxembourg, can participate for free in the development of luxembourgish (ilnas), european (cen, cenelec) and international (iso, iec) standards:. isois the ‘ parent’ part – the fundamental section of the standard that. in this revision of the 11608 family, tc84 has worked to align the various parts, ensuring every potential nis is addressed in the pdf collection of parts, that they integrate well, and topics aren’ t duplicated. iso: (e) introduction the iso 11608 series has traditionally addressed hand- held needle- based injection systems (niss) that are intended for parenteral administration by injection of medicinal products through a needle to humans. s conformance with its design specification. this document is applicable to needle- based injection systems (nis) with automated functions (nis- auto) primarily intended to administer medicinal iso 11608 pdf products to humans. iso: needle- based injection systems for medical use - requirements and test methods - part 1: needle- based injection systems.
this fourth edition cancels and replaces the third edition (iso:), which has been technically revised. 1 – preconditions should be combined if, per risk assessment, high probability of exposure during normal use. the devices described in this document are designed to be used with the devices described in

isoand iso. this document specifies requirements and test methods for on- body delivery systems (obds) needle- based injection systems (niss) for single patient use, intended for subcutaneous, intramuscular or intradermal delivery of a discrete volume (bolus) of medicinal product, through needles or soft cannulas, incorporating pre- filled or user- filled, replaceable or non- replaceable containers. a list of all parts in the iso 11608 series can be found on the iso website. iso: (e) introduction.

this document is also applicable to prefilled syringes (see isowhen used with a nis (see also scope of iso:). iso 11608 consists of the following parts, under the general title needle- based injection systems for medical use — requirements and test methods: — part 1: needle- based injection systems. this document specifies requirements and test methods for needle- based injection systems (niss) for single- patient use intended to deliver discrete volumes (bolus) of medicinal product, which can be delivered through needles or soft cannulas for ferences considerations for combining preconditions prior to performance testing. the sampling plans, preconditioning criteria and other aspects of testing specified in these documents are intended to verify the design at a high confidence level. this european standard en iso: was adopted as luxembourgish standard ilnas- en iso:. — part 2: needles. the first edition of this document, i. containers covered in iso: include single- and multi- dose syringe- based and cartridge- based systems, filled either by the manufacturer or by the end- user. the main changes are as follows: — test methods and dimensions specific to traditional pen- injector “ type a” cartridges have been removed.

the iso 11608 series includes requirements for design verification of the nis? this document is not applicable to the following products: — sterile hypodermic needles; — sterile hypodermic syringes; — sterile single- use syringes, with or without needle, for insulin;. this document is intended to be used in conjunction with iso. fda recommends combining preconditions for.