Reference standard list

Item	Standard・Standard number	Standard・Standard name
Principle	ISO/TR16142-1:2016	Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
	93/42/EEC	Medical Devices Directive
	The 145th of laws August 10, 1960	Pharmaceuticals and Medical Devices Law
Quality	EN ISO 13485:2012/AC:2012	Medical devices - Quality management systems - Requirements for regulatory purposes
	JIS Q 13485:2005	Medical equipment—Quality management system—Claims postulated for restriction purpose
	The 169th of public welfare Labor ministerial ordinances 2004.12.17	Ministerial ordinance medicine about good manufacturing practice of medical equipment and in vitro diagnostic
Risk	EN ISO 14971:2012	Medical devices — Application of risk management to medical devices
	JIS T 14971:2000	Medical equipment—Application of risk management to medical equipment
Chemistry claims postulated	EN ISO 10993-1:2009 /AC:2010	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
	ISO 10993-2:2006	Biological evaluation of medical devices -- Part 2: Animal welfare requirements
	EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3:Tests for genotoxicity carcinogenicity andreproductive toxicity
	EN ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
	EN ISO 10993-7:2008 /AC:2009	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
	ENISO 10993-10:2013	Biological evaluation of medical devices -Part 10:Tests for irritation and skin sensitization
	ISO 10993-11:2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
	EN ISO 10993-12:2012	Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
	EN ISO 10993-18:2009	Biological evaluation of medical devices-Part18:Chemical characterization of materials
	JIS T 0993-1:2012	Biological evaluation of medical devices -- Part 1: Evaluation and testing
	JIS T 0993-7:2012	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
	Yakushokuki No.1109,1 2011.11.9	About handling on the Pharmaceutical Affairs Law with establishment of Japanese Industrial Standards about the ethylene oxide sterilization residue of medical equipment
	Yakushokukihathu0301,20 2012.3.1	Biological safety necessary for manufacturing (import) and application for approval of medical devices About a basic idea of the examination.
	Seventeen Edithon	Japanese Pharmacopoeia
	Eight Edithon	European Pharmacopoeia
Chemistry claims postulated	Iyaku No.1079 1998.12.11	About the sterilization ending fluid infusion set standard
Physical demands	ISO 594-1:1986	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements
	EN 1616:1997	Sterile urethral catheters for single use
	EN 13868:2002	Catheters-Test methods for kinking of single lumen catheters and medical tubing
	JIS T 3214:2011	Urethral Catheters
	Internal standards	Kinking
	Internal standards	Chemical compatibilitytest
Aseptic guarantee	EN ISO 11135:2014	Sterilization of health care products -- Ethylene oxide -- Requirements for development, validation and routine control of a sterilization process for medical devices
	ISO 11138-01:2017	Sterilization of health care products - Biological indicators- Part 1:General requirements
	ISO 11138-01:2017	Sterilization of health care products - Biological indicators- Part 2:Biological indicators for ethylene oxide sterilization processes
	JIS T 0801-1:2016	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
	Yakuseikukannma No.0215,13 2017.2.15	About establishment of the validation of sterilization standard
Package	EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
	EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
	Jimurennraku 2014.3.14	About a sterilization medical equipment wrapping guideline (industry group making guideline)

Item	Standard・Standard number	Standard・Standard name
Information	ISO 1000:1992	SI units and recommendations for the use of their multiples and of certain other units
	EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"- part 1: Requirements for terminally sterilized medical devices
	EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
	JIS Z 8203:2000	SI units and recommendations for the use of their multiples and of certain other units
	The 51th of public welfare labor ministerial ordinances 1992.5.20	The Measurement Law
	The 85th of public welfare labor ministerial ordinances 1994.7.1	The Product Liability Law
	The 134th of public welfare labor ministerial ordinances 1962.5.15	The Law for Prevention of Unjustified premiums and False labeling
	Yaku No.1339 1980.10.9	Standard of proper advertisement of medicine
	Iyakushin No.202 1979.9.30	Revision of ministerial ordinance that provides synthetic color that can be used for medicine by deletion of non-legal measurement
	Iyakushin No.205 1979.9.30	About the handling of manufacturing (import) and the application for approval of the medicine by the deletion of non-legal measurement
	Yakushoku No.0709004 2004.7.9	Law that revises a part of drug legislation and collecting blood and blood donation mean occupation
	Yakushokukannma No.0331 008 2005.3.31	About the display such as the medicines by the revision drug legislation
	Yakushoku No.0310003 2005.3.10	About the writing method of medical equipments information
Reliability	MEDDEV 2.7/1 rev.4:2016	GUIDELINES ON A MEDICAL DEVICES CLINICAL EVALUATION:A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
	MEDDEV 2.12/2 rev.2:2012	GUIDELINES ON MEDICAL DEVICES POST MARKET CLINICAL FOLLOW-UP STUDIES
Usability	IEC 62366-01Edition1.0:2015-02	Medical devices-Application of usability engineering to medical devices
Vigilance	MEDDEV 2.12/1 rev.8:2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
Others	ISO 14644-01:2015	Cleanrooms and associated controlled environments- Part 1 :Classification of air cleanliness
	ISO 14644-02:2015	Cleanrooms and associated controlled environments - Part 2 :Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
	ISO 14698-01:2003	Cleanrooms and associated controlled environments - Part 1 :Classification of air cleanliness by particle concentration
	ISO 14698-02:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
	EN ISO 11737-01:2006	Sterilization of medical devices-Microbiological methods - Part 1:Determination of a population of microorganisms on products
	EN ISO 11737-02:2009	Sterilization of medical devices -Microbiological methods - Part 2 : Tests of sterility performed in the definition, validation and maintenance of asterilization process

*Our applicable standard is included besides the above-mentioned.

Validity of not using harmonized standards

Harmonized standard・standard number	Alternative standard・standard number	Analysis results
EN 1616:1997	JIS T 3214:2011	The left alternative standards are equal to or surpassing the harmonized standards, and therefore it was judged not problematic to perform evaluation using the alternative standards.
-	Internal standards ・Chemical compatibilitytest	We evaluated by our standard since there is no standard for interaction between disinfectan and catheter in harmonized standard, ISO and EP. Evidence of Effectiveness 1. There is no problem in comparison between theDisinfectan used in the method and the disinfectan used in Europe. - The disinfectan provided in European Pharmacopoeia. - The disinfectan that is described as mutual influence is only SUS and Latex in the Interview Form and instruction for use. Therefore, we judged that there is not the mutual influence between the nutrient and silicone catheter. 2. The test is based on the condition of actual use -It was confirmed that there is no difference between the blank sample and the sample that medication that is assumed to be used was applied as a result of confirmation of deterioration condition. 3. For toxicity of the device - The catheter passed the elution test, and we judged that it is safe chemically.

Reference standard list

Item	Standard・Standard number	Standard・Standard name
Principle	ISO/TR16142-1:2016	Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
	93/42/EEC	Medical Device Directive
	The 145th of laws August 10, 1960	Pharmaceuticals and Medical Devices Law
Quality	EN ISO 13485:2012/AC:2012	Medical equipment-Quality management system-Claims postulated for restriction purpose
	JIS Q 13485:2005	Medical equipment-Quality management system-Claims postulated for restriction purpose
	The 169th of public welfare labor ministerial ordinances 2004.12.17	Ministerial ordinance medicine about good manufacturing practice of medical equipment and in vitro diagnostic
Risk	EN ISO 14971:2012	Medical equipment-Application of risk management to medical equipment
	JIS T 14971:2000	Medical equipment-Application of risk management to medical equipment
Chemistry claims postulated	EN ISO 10993-1:2009 /AC:2010	Biological evaluation of medical devices -- Part 1: Evaluation and testing
	ISO 10993-2:2006	Biological evaluation of medical devices -- Part 2: Animal welfare requirements
	EN ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
	EN ISO 10993-7:2008 /AC:2009	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
	EN ISO 10993-10:2013	Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity
	EN ISO 10993-12:2012	Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
	EN ISO 10993-18:2009	Biological evaluation of medical devices-Part18:Chemical characterization of materials
	JIS T 0993-1:2012	Biological evaluation of medical devices -- Part 1: Evaluation and testing
	JIS T 0993-7:2012	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
	Yakushokuki No.1109,1 2011.11.9	About handling on the Pharmaceutical Affairs Law with establishment of Japanese Industrial Standards about the ethylene oxide sterilization residue of medical equipment
	Yakushokukihathu No.0301.20 2012.3.1	Biological safety necessary for manufacturing (import) and application for approval of medical devices About a basic idea of the examination.
	Seventeen Edithon	Japanese Pharmacopoeia
	Eight Edithon	European Pharmacopoeia
Chemistry claims postulated	Iyaku No.1079 1998.12.11	About the sterilization ending fluid infusion set standard
Physical demands	JIS T 3236:2011	Styptic balloon
	EN 13868:2002	Catheters-Test methods for kinking of single lumen catheters and medical tubing
	Internal standards	-Strength of shaft -Test to the fit of funnel and connecting tool -Verification of air leak in balloon -Chemical compatibilitytest
Aseptic guarantee	EN ISO 11135 : 2014	Sterilization of health care products -- Ethylene oxide -- Requirements for development, validation and routine control of a sterilization process for medical devices
	ISO 11138-01:2017	Sterilization of health care products - Biological indicators- Part 1:General requirements
	ISO 11138-02:2017	Sterilization of health care products - Biological indicators- Part 2:Biological indicators for ethylene oxide sterilization processes
	JIS T 0801-1:2016	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
	Yakuseikukannma No.0215,13 2017.2.15	About establishment of the validation of sterilization standard
Package	EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
	EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
	Jimurennraku 2014.3.14	About a sterilization medical equipment wrapping guideline (industry group making guideline)

Item	Standard・Standard number	Standard・Standard name
Information	ISO 1000:1992	SI units and recommendations for the use of their multiples and of certain other units
	EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"- part 1: Requirements for terminally sterilized medical devices
	EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1:General requirements
	EN 15986:2011	Symbols for use in the labelling of medical devices —Requirements for labelling of medical devices containing phthalates
	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
	JIS Z 8203:2000	SI units and recommendations for the use of their multiples and of certain other units
	The 51th of public welfare labor ministerial ordinances 1992.5.20	The Measurement Law
	The 85th of public welfare labor ministerial ordinances 1994.7.1	The Product Liability Law
	The 134th of public welfare labor ministerial ordinances 1962.5.15	The Law for Prevention of Unjustified premiums and False labeling
	Yaku No.1339 1980.10.9	Standard of proper advertisement of medicine
	Iyakushin No.202 1979.9.30	Revision of ministerial ordinance that provides synthetic color that can be used for medicine by deletion of non-legal measurement
	Iyakushin No.205 1979.9.30	About the handling of manufacturing (import) and the application for approval of the medicine by the deletion of non-legal measurement
	Yakushoku No.0709004 2004.7.9	Law that revises a part of drug legislation and collecting blood and blood donation mean occupation
	Yakushokukannma No.0331 008 2005.3.31	About the display such as the medicines by the revision drug legislation
	Yakushoku No.0310003 2005.3.10	About the writing method of medical equipments information
Reliability	MEDDEV 2.7/1 rev.4:2016	GUIDELINES ON A MEDICAL DEVICES CLINICAL EVALUATION:A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
	MEDDEV 2.12/2 rev.2:2012	GUIDELINES ON MEDICAL DEVICES POST MARKET CLINICAL FOLLOW-UP STUDIES
Usability	IEC 62366-01 Edition1.0 :2015-02	Medical devices-Application of usability engineering to medical devices
Others	ISO 14644-01:2015	Cleanrooms and associated controlled environments- Part 1 :Classification of air cleanliness
	ISO 14644-02:2015	Cleanrooms and associated controlled environments - Part 2 :Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
	ISO 14698-01:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part1: General principles and methods
	ISO 14698-02:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
	EN ISO 11737-01:2006	Sterilization of medical devices-Microbiological methods - Part 1:Determination of a population of microorganisms on products
	EN ISO 11737-02:2009	Sterilization of medical devices -Microbiological methods - Part 2 : Tests of sterility performed in the definition, validation and maintenance of asterilization process

*Our applicable standard is included besides the above-mentioned.

Validity of not using harmonized standards

Harmonized standard・ standard number	Alternative standard・ standard number	Analysis results
-	Internal standards -Strength of shaft -Test to the fit of funnel and connecting tool -Verification of air leak in balloon	Because the harmonized standard for physical requirements of the product is lacking, our own standard has been set.
-	Internal standards -Chemical compatibilitytest	We evaluated by our standard since there is no standard for interaction between nutrient and catheter in harmonized standard, ISO and EP. Evidence of Effectiveness 1. There is no problem in comparison between the nutrient used in the method and the nutrient used in Europe. - The nutrient that is sold in Europe is used. - The material that is described as mutual influence is only polyvinyl chloride in the Interview Form. Therefore, we judged that there is not the mutual influence between the nutrient and silicone catheter. 2. The test is based on the condition of actual use - We confirmed that there was no abnormality on the catheter when the catheter was soaked in the nutrient for over the period of use with normal indwelling condition. 3. For toxicity of the device - The catheter passed the elution test, and we judged that it is safe chemically.

Reference standard list

Item	Standard・Standard number	Standard・Standard name
Principle	ISO/TR16142-1:2016	Medical devices-Recognized essential principles of safety and performance of medical devices
	93/42/EEC	Medical Device Directive
	The 145th of laws August 10, 1960	Pharmaceuticals and Medical Devices Law
Quality	EN ISO 13485:2012/AC:2012	Medical equipment—Quality management system—Claims postulated for restriction purpose
	JIS Q 13485:2005	Medical equipment—Quality management system—Claims postulated for restriction purpose
	The 169th of public welfare Labor ministerial ordinances 2004.12.17	Ministerial ordinance medicine about good manufacturing practice of medical equipment and in vitro diagnostic
Risk	EN ISO 14971:2012	Medical equipment—Application of risk management to medical equipment
	JIS T 14971:2000	Medical equipment—Application of risk management to medical equipment
Chemistry claims postulated	EN ISO 10993-1:2009 /AC:2010	Biological evaluation of medical devices -- Part 1: Evaluation and testing
	ISO 10993-2:2006	Biological evaluation of medical devices -- Part 2: Animal welfare requirements
	EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3:Tests for genotoxicity carcinogenicity and reproductive toxicity
	EN ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
	EN ISO 10993-7:2008 /AC:2009	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
	EN ISO 10993-10:2013	Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity
	ISO 10993-11:2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
	EN ISO 10993-12:2012	Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
	EN ISO 10993-18:2009	Biological evaluation of medical devices-Part18:Chemical characterization of materials
	JIS T 0993-1:2012	Biological evaluation of medical devices -- Part 1: Evaluation and testing
	JIS T 0993-7:2012	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
	Yakushokuki No.1109,1 2011.11.9	About handling on the Pharmaceutical Affairs Law with establishment of Japanese Industrial Standards about the ethylene oxide sterilization residue of medical equipment
	Yakushokuki0301,20 2012.3.1	Biological safety necessary for manufacturing (import) and application for approval of medical devices About a basic idea of the examination.
	Seventeen Edithon	Japanese Pharmacopoeia
	Eight Edithon	European Pharmacopoeia
Chemistry claims postulated	Iyaku No.1079 1998.12.11	EN 1615:2000
Physical demands	EN 1615:2000	Enteral feeding catheters and enteral giving sets for single use and their connectors. Design and testing
	EN 1618:1997	Catheters other than intravascular catheter-Test methods for common properties
	EN 13868:2002	Catheters-Test methods for kinking of single lumen catheters and medical tubing
	ISO 80369-3:2016	Small-bore connectors for liquids and gases in healthcare applications -- Part 3: Connectors for enteral applications
	JIS T 3213:2011	Enteral feeding catheters and enteral giving sets
	Iyaku No.888 2000.8.31	About the enactment of the standard concerning medical devices to prevent the malpractice etc.
	Internal standards	・Characteristics of the balloon ・Verification of the flow rate of nutrient ・Chemical compatibility test
Aseptic guarantee	EN ISO 11135:2014	Sterilization of health care products -- Ethylene oxide -- Requirements for development, validation and routine control of a sterilization process for medical devices
	ISO 11138-01:2017	Sterilization of health care products - Biological indicators- Part 1:General requirements
	ISO 11138-01:2017	Sterilization of health care products - Biological indicators- Part 2:Biological indicators for ethylene oxide sterilization processes
	JIS T 0801-1:2016	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
	Yakuseikannma No.0215,13 2017.2.15	About establishment of the validation of sterilization standard

Item	Standard・Standard number	Standard・Standard name
Package	EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
	EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
	Jimurennraku 2014.3.14	About a sterilization medical equipment wrapping guideline (industry group making guideline)
Information	ISO 1000:1992	SI units and recommendations for the use of their multiples and of certain other units
	EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"- part 1: Requirements for terminally sterilized medical devices
	EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
	JIS Z 8203:2000	SI units and recommendations for the use of their multiples and of certain other units
	The 51th of public welfare labor ministerial ordinances 1929.5.20	The Measurement Law
	The 85th of public welfare labor ministerial ordinances 1931.7.1	The Product Liability Law
	The 134th of public welfare labor ministerial ordinances 1962.5.15	The Law for Prevention of Unjustified premiums and False labeling
	Yaku No.1339 1980.10.9	Standard of proper advertisement of medicine
	Iyakushin No.202 1997.9.30	Revision of ministerial ordinance that provides synthetic color that can be used for medicine by deletion of non-legal measurement
	Iyakushin No.205 1997.9.30	About the handling of manufacturing (import) and the application for approval of the medicine by the deletion of non-legal measurement
	Yakushoku No.0709004 2004.7.9	Law that revises a part of drug legislation and collecting blood and blood donation mean occupation
	Yakushokukannma No.0331 008 2005.3.31	About the display such as the medicines by the revision drug legislation
	Yakushoku No.0310003 2005.3.10	About the writing method of medical equipments information
Reliability	MEDDEV 2.7/1 rev.4:2016	GUIDELINES ON A MEDICAL DEVICES CLINICAL EVALUATION:A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
	MEDDEV 2.12/2 rev.2:2012	GUIDELINES ON MEDICAL DEVICES POST MARKET CLINICAL FOLLOW-UP STUDIES
Usability	IEC 62366-01Edition1.0:2015-02	Medical devices-Application of usability engineering to medical devices
Vigilance	MEDDEV 2.12/1 rev.8:2013	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
Others	ISO 14644-01:2015	Cleanrooms and associated controlled environments- Part 1 :Classification of air cleanliness
	ISO 14644-02:2015	Cleanrooms and associated controlled environments - Part 2 :Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
	ISO 14698-01:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part1: General principles and methods
	ISO 14698-02:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
	EN ISO 11737-01:2006	Sterilization of medical devices-Microbiological methods - Part 1:Determination of a population of microorganisms on products
	EN ISO 11737-02:2009	Sterilization of medical devices -Microbiological methods - Part 2 : Tests of sterility performed in the definition, validation and maintenance of a sterilization process

*Our applicable standard is included besides the above-mentioned.

Validity of not using harmonized standards

Harmonized standard・standard number	Alternative standard・standard number	Analysis results
-	Internal standards ・Characteristics of the balloon	Because the harmonized standard for physical requirements of the product is lacking, our own standard has been set.
-	Internal standards ・Verification of the flow rate of nutrient	Because the harmonized standard for physical requirements of the product is lacking, our own standard has been set.
-	Internal standards ・Chemical Compatibility test	We evaluated by our standard since there is no standard for interaction between comparison and catheter in harmonized standard, ISO and EP. Evidence of Effectiveness 1. There is no problem in comparison between the comparison used in the method and the comparison used in Europe. - The comparison that is sold in Europe is used. - The material that is described as mutual influence is not in the Interview Form. Therefore, we judged that there is not the mutual influence between the comparison and silicone catheter. 2. The test is based on the condition of actual use - We confirmed that there was no abnormality on the catheter when the catheter was soaked in the comparison for over the period of use with normal indwelling condition. 3. For toxicity of the device - The catheter passed the elution test, and we judged that it is safe chemically.