



2

17.04.2015 . 10:00

107/14.04.2015 .

- : - . .- .-
- : . .-
- . .- ()
- . .- .-
- . .- ,
- . .-
- . .-

I. .68, .7
1

1.

46, 1 1 : - 34
. 56, . 1, . 14 .
/ ,

II-

1.1.

, : 46 10,45 .
46 11,45
1 .,

5 ()

1 .

46

2.

4 1 : - 50,
100, 101 102, . 56, . 1, . 14 .
/ ,

/ , , II- ,
 .
 3. :
 1 1 - 105
 107, , / . 56, . 1, . 14 .
 ,

II- .
 4. :
 7 1,
 - 19, 24, 47, 48, 51, 61 62,
 . 56, . 1, . 14 ,
 ,
 II-

4.1. :
 ISO 9001:2008 . . . ,
 Turkuaz Saglik Hizmetleri Medikal Temizlik Kimyasal Urunler San. ve Tic.Ltd.Sti.,
 ISO 13485:2003

4.1.1. 19, 47 48 - . . . ;
 4.1.2. 19 - . ;
 4.1.3. 19 - Turkuaz Saglik Hizmetleri Medikal
 Temizlik Kimyasal Urunler San. ve Tic.Ltd.Sti.

5 ()
 ISO 13485:2003
 / / . . . ,
 Turkuaz Saglik Hizmetleri Medikal Temizlik Kimyasal Urunler San. ve Tic.Ltd.Sti.,
 (,
 ” ”).

5. :
 1 1 343,
 , / . 56, . 1, . 14 .
 / , /
 , , II- .

6. 91 :
 15 1,
 - 222, 223, 224, 225, 237, 238, 250, 255, 256, 259, 261, 262, 287, 288 289,
 , . 56, . 1, . 14 /
 , / , /
 , II- .

7. :

257, 258, 260, 261, 326, 327, 328, 329, 330, 331, 332 333, .56, .1, .14 / ,

II-

8.

6, 7, 21, 101, 102, 103, 116, 117, 118 132, .56, .1, .14 . -3,

II-

8.1.

ISO 9001:2008 Teleflex Medical GmbH,
ISO 13485:2003 o .

5 ()

ISO 13485:2003

Teleflex Medical GmbH.,

(, ”). ”

9.

191, 192, 195, 198, 202, 205, 210, 222, 223, 224, 225, 238, 242, 255, 259, 261, 262, 264, 284, 285, 286, 326, 327, 328, 329, 330, 331, 332 333, .56, .1, .14 . / ,

II-

10.

1 1 : 305, .56, .1, .14 . / , II-

11.

22 1, - 35, 36, 37, 44, 45, 74, 76, 77, 78, 79, 80, 81, 82, 84, 85, 87, 88, 89, 90, 92, 96 334, .56, .1, .14 . / , II-

12.

:

115, 169, 170, 171, 173, 174, 176, 177, 8 1 -
.56, .1, .14 . ,

12.1. 1 , : 170 II-
B.V., ISO 9001:2008 ISO
13485:2003 .

5 () ISO 13485:2003
B.V.,
(, ,
„ ”).

13. :
1 1 -
257, 258, 261, 304, 311, 312 314, .
56, .1, .14 . / ,
II- .

14. :
1 1 -
257, 258, 260, 261, 262, 263, 312 314, .
.56, .1, .14 . / ,
II- .

15. :
9 1,
- 42, 301, 302, 306, 307, 308, 309, 310 311, .
.56, .1, .14 . / ,
II- .

16. :
1 1 - 70,
191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 210, 215, 217, 218, 222,
223, 224, 225, 238, 242, 254, 293, 294, 295, 296, 297 298, .
.56, .1, .14 . ,
II-

16.1. : 292,75 .
293,18 . 0,43 .

16.2.

ISO 9001:2008

ISO 13485:2003

”
o

5 ()

: 1.

0,43 ; 2.

ISO 13485:2003

”

”

”).

17.

:

1 1
257, 258, 260, 261, 262, 263, 264, 265, 283, 284, 285, 286 312,
. 56, . 1, . 14 .
/

—

,

,

II-

18.

:

1 1
100, 104 342, , . 56, . 1, . 14
/

—

,

,

II-

19.

:

1 1
90, 92 94, , . 56, . 1, . 14 - 87,
/

—

,

,

II-

20.

:

1 1
37, , . 56, . 1, . 14 - 35
/

—

,

,

II-

21.

:

1 1
72, 73, 74, 77, 78, 79, 87, 88, 89, 90, 91, 92, 93, 94 156. - 14,
. 56, . 1, . 14

—

:

-

,

,

,

,

—

3

-

;

-

. 56, . 1, . 14

,

”

”

.

5 ()

: 1.

_____, _____
/ 3/; 2. .56, .1, .14

22.

6 1,
- 87, 90, 91, 92, 93 94,
.56, .1, .14

:

23.

1 1
178, 181, 182, 183, 184, 188, 189, 191, 192, 194, 195, 197, 198, 199, 200, 201, 202, 203, 205, 232, 240,
242, 244, 246, 247, 248, 315, 316, 318, 319, 320, 326, 327, 328 329,
.56, .1, .14

:

II-

24.

29 1,
- 16, 40, 46, 87, 88, 90, 91, 92, 93, 94, 105, 106, 113, 257, 261, 284, 285, 286, 291, 293, 295,
296, 297, 311, 326, 327, 328, 329 330,
.56, .1, .14

:

II-

24.1.

16

ISO 9001:2008

ISO 13485:2003

5 ()

ISO 13485:2003

25.

1 1
191, 192, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 205, 206, 210, 215, 217, 219, 220, 222, 223,
224, 225, 230, 232, 236, 238, 239, 240, 242, 253, 254, 257, 258, 260, 261, 264, 293, 294, 295, 296
297,
.56, .1, .14

:

25.1.

10,80 . 9 ., 199 199 1,80 .

5 ()

199

9 .

26.

28 1, - 8, 10, 11, 16, 18, 20, 21, 24, 34, 35, 36, 40, 44, 46, 62, 64, 75, 76, 86, 87, 88, 89, 90, 91, 92, 93, 94 112, . 56, . 1, . 14 / , II- , .

27.

9 1, - 33, 257, 258, 261, 262, 263, 264, 303 312, . 56, . 1, . 14 / , II- , .

28.

1 1 . 56, . 1, . 14 305, / , II- , .

29.

2000 : 22 1, - 40, 41, 42, 43, 44, 45, 72, 88, 89, 90, 91, 92, 93, 94, 95, 148, 149, 150, 151, 154, 346 347, . 56, . 1, . 14 / , II- , .

30.

3 1, - 34, 36 46, 56, . 1, . 14 / , II- , .

31.

111 1,
 – 1, 3, 4, 5, 7, 8, 9, 12, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 29, 30, 33, 35,
 36, 37, 38, 39, 40, 41, 42, 46, 47, 50, 51, 53, 55, 56, 58, 60, 62, 65, 66, 68, 69, 70, 71, 72, 74, 75, 76, 81,
 87, 90, 91, 92, 93, 94, 96, 98, 112, 113, 120, 121, 122, 123, 124, 125, 126, 127, 130, 140, 141, 146, 178,
 179, 180, 181, 182, 184, 185, 186, 187, 254, 257, 258, 260, 261, 262, 263, 273, 274, 275, 276, 277, 279,
 280, 282, 291, 293, 294, 295, 296, 297, 304, 312, 313, 316, 325, 336 347,
 , . 56, . 1, . 14

II-

31.1.

96
 ISO 9001:2008 TNI Chirurgisches
 Nadelwerk GmbH, ISO 13485:2003
 5 ()
 ISO 13485:2003
 TNI Chirurgisches Nadelwerk GmbH,
 (,
 „ ”).

32.

2 1,
 – 1 257, 258, 260, 261, 263, 267, 268, 272, 274, 275, 276, 281, 286,
 304, 312, 313; 1 305,
 . 56, . 1, . 14 . / ,

II-

33.

1 1 : – 21,
 23, 38, 51, 66, 68, 69, 129, 130, 175 345, ,
 . 56, . 1, . 14 . ,
 II-

ISO 13485:2003

(,
 „ ”).

5 ()

ISO 13485:2003

(,
 „ ”).

34.

17 1,
- 2, 3, 8, 26, 29, 30, 38, 40, 41, 60, 148, 149, 150, 151, 153, 154 155,
. 56, . 1, . 14

II-

35.

27 1,
-1, 8, 9, 10, 11, 12, 16, 18, 20, 21, 22, 24, 25, 34, 36, 38, 39, 40, 41, 42, 46, 52, 55, 61, 62, 64
66, . 56, . 1, . 14

II-

35.1.

ISO 9001:2008

ISO 13485:2003

5 ()

ISO 13485:2003

”).

36.

20 1,
- 42, 43, 58, 59, 60, 66, 110, 148, 149, 150, 151, 153, 154, 155, 156, 162, 163, 164, 165
166, . 56, . 1, . 14

II-

37.

11 1,
- 16, 17, 44, 45, 75, 76, 81, 101, 102, 112 113,
. 56, . 1, . 14

. 56, . 1, . 14

1

16

M

ISO 9001:2008

ISO13485:2012

5 ()

: 1.

ISO 13485:2003

(, ”)
1 16,
ISO 9001:2008 ISO13485:2012

38. :
1 1 - 8,
16, 18, 34, 40, 42, 44, 46, 50, 61, 64, 66, 68, 70, 112 113,
.56, .1, .14 .

II-

38.1. :
ISO 9001:2008

.. Yancheng Huida Medical Instruments Co. Ltd,
ISO 13485:2003

5 ()
ISO 13485:2003

Yancheng Huida Medical Instruments Co. Ltd.,
(, ”).

39. :
1 1 341,
.56, .1, .14 .

II-

40. :
52 1,
- 16, 18, 24, 33, 34, 40, 42, 46, 50, 51, 53, 55, 62, 63, 64, 66, 69, 70, 112, 113, 178, 179, 180,
181, 182, 183, 185, 186, 187, 188, 189, 240, 241, 242, 243, 291, 292, 293, 294, 295, 296, 297, 298, 300,
315, 316, 319, 320, 325, 335, 336 337
.56, .1, .14 .

II-

40.1. :
33, 319, 320, 325, 335,

336 337 492,85 .
40.2. , 1 16
ISO 13485:2003

40.3. , 1 33
ISO 13485:2003

VWR ;
40.4. , 1 42
ISO 13485:2003

& . ;

40.5. , 1 66
ISO9001:2008

42. 42

40.6. 1 42 / 66;
, 1 178
ISO 13485:2003

40.7. . . ;
, 1 292
ISO9001:2008 VWR 42.

1 42 / 292;

5 ()

: 1.

33, 319,

ISO

320, 325, 335, 336 337 492,85 .; 2.

13485:2003

. . . , VWR

& . . , . . . ,

(
”); 3. , 1 ”

42 /

66

4.

1

42

/

292

41.

:

257, 258, 261, 262, 263, 264, 284, 285, 286, 304, 312 314,
. 56, . 1, . 14 .

/

II-

. 68, . 8

:/ /

:/ /

...../ /

...../ /

...../ /

...../ /

...../ /

